IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

American Biosystems, Inc.,

Plaintiff,

v.

Civil Action No.

00-2646 DWF/SRN

Electromed, Inc.,

Defendant.

ANSWER TO COMPLAINT AND COUNTERCLAIM

For its Answer to the Complaint of Plaintiff American Biosystems, Inc. ("American Biosystems"), Defendant Electromed, Inc. ("Electromed") hereby states as follows:

1. Answer to Paragraph 1 of the Complaint:

Electromed denies that it is infringing U.S. Patent No. 6,036,662 ("the '662 patent"). In all other respects, Electromed lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1, and therefore denies the same.

2. Answer to Paragraph 2 of the Complaint:

Electromed manufactures a Medpulse™ Respiratory Vest System which does not use the subject matter of the '662 patent and does not infringe the '662 patent. The remaining allegations are vague and indefinite as they do not identify one or more claims of the '662 patent that are alleged to be infringed by Electromed's Medpulse™

Respiratory Vest System. Electromed admits that it has no license or right to use American Biosystems' alleged patented technology. Electromed denies that it is utilizing the same type of oscillatory pressure system that is the subject matter of the '662 patent. Electromed denies that its product infringes American Biosystems' (claims of the '662 patent). Electromed reserves the right to supplement and amend its answer if American Biosystems particularizes its claims alleged in Paragraph 2.

3. Answer to Paragraph 3 of the Complaint:

Electromed lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies such allegations.

4. Answer to Paragraph 4 of the Complaint:

Electromed admits that it is a corporation organized and existing under the laws of Minnesota and denies that its principal place of business is in Minnetonka, Minnesota.

5. Answer to Paragraph 5 of the Complaint:

The allegations of Paragraph 5 state a legal conclusion that does not require an answer. Electromed denies that American Biosystems has any meritorious claim against it.

6. Answer to Paragraph 6 of the Complaint:

Electromed admits that American Biosystems seeks to invoke the jurisdiction of this Court pursuant to 28 U.S.C. §§ 1331 and 1338.

7. Answer to Paragraph 7 of the Complaint:

Electromed admits that it resides in the District of Minnesota and that American

Biosystems alleged that venue is proper in this district. Electromed denies that American Biosystems has any meritorious claim against it. Electromed further denies that it has committed acts of infringement in this district or any other district of the United States of America.

8. Answer to Paragraph 8 of the Complaint:

Electromed admits that a copy of the '662 patent was attached to the Complaint. Electromed denies that the '662 patent was duly and legally granted to American Biosystems, and that this patent is valid or enforceable or has been infringed by Electromed. In all other respects, Electromed lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 8, and therefore denies such allegations.

9. Answer to Paragraph 9 of the Complaint:

No answer is required.

10. Answer to Paragraph 10 of the Complaint:

Electromed admits the allegations of Paragraph 10 of the Complaint. Electromed denies that its Medpulse™ Respiratory Vest System infringes the '662 patent.

11. Answer to Paragraph 11 of the Complaint:

Electromed denies all allegations of Paragraph 11 of the Complaint.

12. Answer to Paragraph 12 of the Complaint:

Electromed denies all allegations of Paragraph 12 of the Complaint

13. Answer to Paragraph 13 of the Complaint:

Electromed denies all allegations of Paragraph 13 of the Complaint.

14. Answer to Paragraph 14 of the Complaint:

Electromed denies all allegations of Paragraph 14 of the Complaint.

AFFIRMATIVE DEFENSES

15. Electromed denies that it has infringed the '662 patent, or actively induced infringement of the '662 patent, or committed any act of contributing infringement of the '662 patent.

16. Because American Biosystems has failed in the Complaint to identify any particular claim or claims of the '662 patent, or any products or practice of Electromed applicable to a claim that is alleged to infringe, Electromed asserts, on information and belief, that the claims of the '662 patent as a whole are invalid for one or more of the reasons set forth below. Electromed reserves the right to supplement and amend these defenses if American Biosystems particularizes its claims and as discovery and trial preparation progress.

17. U.S. Patent No. 6,036,662 is invalid and unenforceable because, inter alia, such patent was not obtained in a manner consistent with and as required by the provisions of Title 35 of the United States Code, in that the '662 patent fails to comply with one or more of the required conditions for patentability for patent claims and specifications (see 35 U.S.C. §§ 102, 103 and 135) and the requirements for patent claims and specifications (see 35 U.S.C. §§ 101 and 112). Under 35 U.S.C. § 282, Electromed shall give notice to the American Biosystems of any patent or publication to be relied upon at least thirty days before trial.

18. The claims of the '662 patent are also invalid for failure to comply with the requirements of 35 U.S.C. § 112, ¶¶ 1 and 2. Claims of this patent are invalid for failure of the specification to (1) "contain a written description of the invention" and/or (2) contain a written description "of the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112, ¶¶ 1 and 2. Claims of this patent are also invalid for failure to "particularly point[] out and distinctly claim[] the subject matter which" American Biosystems regarded as the invention. 35 U.S.C. § 112, ¶ 2.

19. U.S. Patent No. 6,036,662 is invalid, void, and unenforceable because the patent has been misused by American Biosystems in a wrongful attempt to monopolize the marketing of chest compression devices that are not claimed in the '662 patent and are present in the prior art chest compression devices.

20. American Biosystems does not have a reasonable basis for finding infringement of the '662 patent of Electromed's Medpulse™ Respiratory Vest System or any other product made, used or sold by Electromed.

21. American Biosystems knows, or on a reasonable investigation knows, or should know that the allegations of infringement of the '662 patent by Electromed are baseless and made in bad faith.

COUNTERCLAIM FOR DECLATORY RELIEF

Counterclaimant Electromed for its Counterclaim against American Biosystems, alleges as follows:

22. Electromed incorporates by reference Paragraphs 1 through 21, above, as though fully set forth herein.

23. This Counterclaim arises under the patent laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this Counterclaim pursuant to 28 U.S.C. §§ 1331 and 1338, and by reason of the original action filed herein by American Biosystems.

24. This Counterclaim is for declaratory relief under 28 U.S.C. §§ 2201 and 2202.

25. Electromed is a Minnesota corporation with its principal place of business in New Prague, Minnesota.

26. On information and belief, based on allegations in American Biosystems' Complaint, American Biosystems is a Minnesota corporation.

27. On information and belief, American Biosystems claims to be the owner of the '662 patent asserted by the Complaint in this case.

28. An actual and justiciable controversy exists between Electromed and American Biosystems as to the validity, enforceability, and infringement of the '662 patent.

29. U.S. Patent No. 6,036,662 has 12 claims.

30. Claim 1 of the '662 patent is the only independent claim in this patent.

31. Claim 2 to 12 are claims that depend on independent Claim 1 and incorporate by

reference all the limitations of independent Claim 1.

32. Claim 1 of the '662 patent defines an apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

1) an oscillatory air flow generator, comprising

a. an air chamber;
b. a reciprocating diaphragm operably connected with the air chamber;
c. a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;
d. a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and
e. a first motor operably connected with the crankshaft;

2) a continuous air flow generator operably connected with the oscillatory air flow generator;

3) a first feedback and control means operably connected with the oscillatory air flow generator for maintaining the frequency of the oscillatory air flow generator at a predetermined value;

4) and a second feedback and control means operably connected with the continuous air flow generator for continuously varying the output pressure of the continuous air flow generator in order to maintain the peak pressure generated by the positive air flow generator at a predetermined value.

33. The Electromed Medpulse™ Respiratory Vest System alleged by American Biosystems to infringe the '662 patent does not have:

1) c. a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;

1) d. a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and

1) e. a first motor operably connected with the crankshaft;

as defined in Claim 1 of the '662 patent.

34. The Electromed Medpulse™ Respiratory Vest System alleged by American Biosystems to infringe the '662 patent does not have:

2) a continuous air flow generator operably connected with the oscillatory air flow generator:

as defined in Claim 1 of the '662 patent.

35. The Electromed Medpulse™ Respiratory Vest System alleged by American Biosystems to infringe the '662 patent does not have:

3) a first feedback and control means operably connected with the oscillatory air flow generator for maintaining the frequency of the oscillatory air flow generator at a predetermined value:

as defined in Claim 1 of the '662 patent.

36. The Electromed Medpulse™ Respiratory Vest System alleged by American Biosystems to infringe the '662 patent does not have:

4) and a second feedback and control means operably connected with the continuous air flow generator for continuously varying the output pressure of the continuous air flow generator in order to maintain the peak pressure generated by the positive air flow generator at a predetermined value.

as defined in Claim 1 of the '662 patent.

37. American Biosystems has been advised that Electromed's respiratory vest system does not have the structures and functions claimed in Claim 1 of the '662 patent as listed in Paragraphs 33 to 36 herein and does not infringe the '662 patent.

38. There is no reasonable basis for finding infringement of the '662 patent by Electromed's

making, using and selling its Medpulse™ Respiratory Vest System and bringing a claim of infringement of the '662 patent.

39. American Biosystems knows, or on a reasonable investigation knows, or should know that the allegation of infringement of the '662 patent by Electromed's Medpulse™ Respiratory Vest System is baseless.

40. American Biosystems has been advised that the basis in fact for its allegation of patent infringement by Electromed is without merit or foundation and is groundless, frivolous, made in bad faith, or for an improper purpose.

41. American Biosystems has instigated this infringement civil action against Electromed in bad faith and without just cause and in pursuance of a policy to drive Electromed out of business and to monopolize the business of oscillatory chest compression devices throughout the United States of America. American Biosystems' civil action against Electromed, was willfully committed, for purposes of harassment and oppression, with the object of alienating investors, customers and potential customers, and with the intent to subject Electromed to financial hardship, not only for substantial expenses of litigation, but also resulting in substantial loss of sales and profits.

42. American Biosystems having instigated this vexatious and expensive infringement suit herein against Electromed, may dismiss such suit without adjudication of the '662 patent, thereby leaving Electromed and the public subject to further annoyance and litigation.

43. That it is necessary by virtue of the various contentions hereinabove set forth, for the Court to determine and define the rights of the parties hereto in respect thereto.

44. Electromed avers that unless Electromed is found not to infringe the '662 patent or if said patent is not adjudged to be void and invalid, Electromed will be harassed in the manufacture, sale and use of its products.

PRAYER FOR RELIEF

Wherefore, Defendant Electromed, Inc. prays for the following judgment and relief:

A. That the Complaint be dismissed with prejudice;

B. That American Biosystems take nothing by its Complaint;

C. That American Biosystems claim for injunctive relief be denied;

D. That it be declared Electromed does not infringe U.S. Patent No. 6,036,662;

E. That U.S. Patent No. 6,036,662 be declared invalid;

F. That U.S. Patent No. 6,036,662 be declared unenforceable;

G. That Electromed be awarded reasonable cost and attorneys' fees pursuant to 35 U.S.C. § 285 and/or 28 U.S.C. § 1927.

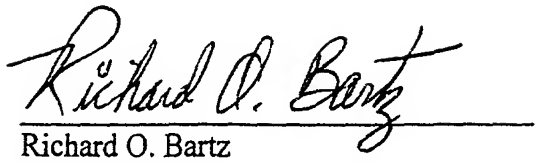
H. That Electromed be granted all other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Electromed sets forth its demand for a jury trial on all issues for which it is entitled for a jury trial.

Dated: December 23, 2000

Respectfully submitted,



Richard O. Bartz
Richard J. Bartz
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435
(952) 920-3959

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that a copy of the Defendant's Answer To Complaint and Counterclaim was mailed by first class mail, postage prepaid, this 23rd day of December, 2000, to Jacob M. Holdreith and Cyrus A. Morton, Oppenheimer, Wolff & Donnelly, L.L.P., 3400 Plaza VII Building, 45 South 7th Street, Minneapolis, Minnesota 55402, Attorneys for Plaintiff.

Richard O. Bartz

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	Case Number: 00-2646 DWF/SRN **REPLY TO COUNTERCLAIM** **JURY TRIAL DEMANDED**

Plaintiff American Biosystems, Inc. ("American Biosystems") for its reply to Defendant Electromed, Inc.'s ("Electromed") counterclaim for declaratory relief states as follows:

1. Paragraph 22 of Electromed's counterclaim purports to incorporate by reference Electromed's Answer and Affirmative Defenses in its counterclaim, it is therefore objected to as an improper pleading under Fed.R.Civ.P. Rule 8(a) and is therefore denied. American Biosystems incorporates by reference the allegations of the Complaint. Moreover, American Biosystems hereby denies all allegations of Defendant's counterclaim that are not specifically admitted.

2. In response to the allegations contained in Paragraph 23 of Defendant's counterclaims, American Biosystems admits Electromed purports to state a counterclaim under 35 U.S.C., admits the Court has subject matter jurisdiction over the asserted claims of the '662 patent, denies that, Electromed is entitled to relief and denies the Court has subject matter over unasserted claims of the '662 Patent.

3. Admits the allegations contained in Paragraph 24 of Defendant's counterclaims, but denies that Defendant is entitled to any relief.

4. Admits that Electromed is a Minnesota corporation but lacks sufficient information to admit or deny the remaining allegations of Paragraph 25 and therefore denies the same.

4. Admits that Electromed is a Minnesota corporation but lacks sufficient information to admit or deny the remaining allegations of Paragraph 25 and therefore denies the same.

5. Admits the allegations contained in Paragraph 26 of Defendant's counterclaim.

6. Admits the allegations contained in Paragraph 27 Defendant's counterclaim.

7. Admits that an actual and justicable controversy exists between Electromed and American Biosystems as to the asserted claims of the '662 Patent but denies the remaining allegations contained in Paragraph 28 of Defendant's counterclaim, if any.

8. Admits the allegations contained in Paragraph 29 of Defendant's counterclaim.

9. Admits the allegations contained in Paragraph 30 of Defendant's counterclaim.

10. Admits the allegations contained in Paragraph 31 of Defendant's counterclaim.

11. Admits the allegations contained in Paragraph 32 of Defendant's counterclaim.

12. Denies the allegations contained in Paragraph 33 of Defendant's counterclaim.

13. Denies the allegations contained in Paragraph 34 of Defendant's counterclaim.

14. Denies the allegations contained in Paragraph 35 of Defendant's counterclaim.

15. Denies the allegations contained in Paragraph 36 of Defendant's counterclaim.

16. Admits that Defendant has alleged that its respiratory vest systems does not have the structures and functions claimed in Claim 1 of the '662 Patent and that the vest system does not infringe the '662 Patent and admits that Defendant has denied infringement in a letter to American Biosystems, but denies the remaining allegations, if any, in Paragraph 37 of Defendant's counterclaim, and specifically states that Defendant's vest system does have the structures and functions claimed in Claim 1 of the '662 Patent as listed in Paragraphs 33-36 of Defendant's counterclaim and infringes the '662 Patent.

17. Denies the allegations contained in Paragraph 38 of Defendant's counterclaim.

18. Denies the allegations contained in Paragraph 39 of Defendant's counterclaim.

19. Admits that Defendant has alleged that American Biosystems patent infringement suit against it is without merit or foundation and is groundless, frivolous, made in bad faith, or for an improper purpose and admits that Defendant has so stated in a letter to American Biosystems, but denies the remaining allegations, if any, in ¶40 of Defendant's counterclaim and specifically states that Defendant has not provided any basis in fact for its allegations and that American Biosystems has not been informed of any basis in fact by Defendant.

20. Denies the allegations contained in Paragraph 41 of Defendant's counterclaim and states that American Biosystems has brought this action against Electromed for the proper purpose of adjudicating American Biosystems' patent rights.

21. Denies the allegations contained in Paragraph 42 of Defendant's counterclaim.

22. Denies the allegations contained in Paragraph 43 of Defendant's counterclaim except that admits that the Court has jurisdiction over the claims of the '662 Patent that are asserted by American Biosystems.

23. Denies the allegations contained in Paragraph 44 of Defendant's counterclaim.

24. Except as expressly admitted, alleged or otherwise qualified heretofore, denies each and every allegation contained in Defendant's counterclaim.

AFFIRMATIVE DEFENSE

U.S. Patent No. 6,036,662 is valid, enforceable, and infringed by Electromed's Respiratory Vest System.

PRAYER FOR RELIEF

American Biosystems prays that:

1. It be granted the relief sought in the Complaint;

2. Electromed's counterclaims be dismissed with prejudice and on the merits and Electromed shall take nothing by its counterclaims;

3. American Biosystems be awarded its costs, disbursements and attorney's fees; and

4. American Biosystems be awarded such further relief as the court may deem just and equitable.

Date: January 11, 2001

OPPENHEIMER WOLFF & DONNELLY LLP

By _____

Jacob M. Holdreith, #211011
Cyrus A. Morton, #287325
3400 Plaza VII Building
45 South 7th Street
Minneapolis, MN 55402
Phone: (612) 607-7000
Fax No.: (612) 607-7100

ATTORNEYS FOR PLAINTIFF

2/16/01

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

American Biosystems, Inc.,

Plaintiff,

v.

Civil Action No.

00-2646 DWF/SRN

Electromed, Inc.,

Defendant.

JOINT RULE 26(f) REPORT

The parties hereby submit the following joint Report pursuant to Rule 26(f) and L.R. 16.2 and the Order of Magistrate Judge Nelson:

1. DATE AND PLACE OF MEETING AND IDENTIFICATION OF PARTIES AND THEIR ATTORNEYS; AGENDA OF MATTERS FOR PRETRIAL CONFERENCE

a. The meeting took place by letter and an exchange of proposed scheduling orders and through a telephone conference on February 6, 2001.

b. Plaintiff

American Biosystems, Inc.
1020 West County Road F
St. Paul, Minnesota 55126

Attorneys:

OPPENHEIMER WOLFF & DONNELLY LLP

Cyrus A. Morton, #287325
David McKinley, #295814
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, Minnesota 55402-1609
Telephone: (612) 607-7000
Facsimile: (612) 607-7100

Defendant

Electromed, Inc.
14920 Minnetonka Industrial Road
Minnetonka, Minnesota 55345

Attorneys:

BARTZ & BARTZ PA

Richard O. Bartz, #5174
Richard J. Bartz, #166364
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435-1983
Telephone: (952) 920-3959
Facsimile: (952) 920-6494

c. The parties believe there are no insurance carriers that may be liable for the defense or payment of any damage award.

d. An agenda of matters to be discussed at the Pretrial Conference:

a) The discovery and dispositive motion schedule

b) Settlement options

c) Submission and response to claim chart

d) Schedule for *Markman* Hearing

2. DESCRIPTION OF CASE

a. This is an action of patent infringement. The Court has jurisdiction over the patent infringement action pursuant to 28 U.S.C. §§ 1331 and 1338.

b. American Biosystems, Inc. ("ABI") alleges as follows: ABI is the owner by assignment of U.S. Patent No. 6,036,662 ("the '662 patent"). The inventors of the device and method disclosed in the '662 patent are Nicholas P. Van Brunt and Donald J. Gagne. The '662 patent claims an apparatus for generating oscillatory air pulses in a bladder positioned about a person. ABI alleges infringement of the '662 patent pursuant to 35 U.S.C. §§ 271, 281 and 283-285.

Electromed, Inc. ("Electromed") denies infringement and contends that the '662 patent is invalid, void and unenforceable, and that the allegations of infringement of the '662 patent are baseless and made in bad faith.

c. ABI alleges damages pursuant to 35 U.S.C. § 284, but is unable to estimate the actual dollar amount of damages it has suffered without discovery.

Electromed has served a counterclaim for declaratory relief pursuant to 28 U.S.C. §§ 2201 and 2202 without seeking damages at this time but reserves the right to claim damages and an award of its attorneys' fees and costs.

3. PLEADINGS

a. The Complaint, Answer and Counterclaim, and Reply to Counterclaim have been served and filed. Neither party is proposing to amend the pleadings at this time.

b. All motions that seek to amend will be filed by October 1, 2001. The parties expect to submit a stipulated protective order to protect confidential information. ABI delivered a draft protective order on January 11, 2001, which Electromed is proceeding to review and advise of

amendments thereto. Until a protective order is approved, ABI proposes that confidentiality shall be governed by N.D. Cal. L.R. 16-6(b), a reference copy of which is attached as Exhibit A.

c. Each party has timely demanded a jury trial.

4. **DISCOVERY PLAN**

a. Initial disclosures have already been exchanged.

b. The parties have engaged in preliminary settlement discussions. The parties do not wish to employ additional alternative dispute resolution at this time.

c. Discovery will not be conducted in phases or limited to particular issues.

d. The parties propose that ABI and Electromed will disclose their experts and expert reports by January 15, 2002 and exchange expert rebuttal reports by February 15, 2002.

e. Each party will serve no more than 50 interrogatories.

f. The parties propose that each party will take no more than 15 depositions (excluding expert depositions).

g. Each party expects to take an expert deposition of each expert the other party discloses. Each party shall take no more than 5 expert depositions.

h. Attached is a proposed pre-trial Scheduling Order. There are only two differences that the parties have. In paragraph 1 of the Discovery Plan, ABI would like 60 days to provide "Plaintiff's Claim Chart." Defendant would like this to take place in 30 days because the '662 patent has only one independent claim, because ABI has stated in its initial disclosures that it has Electromed's MedPulse 2000 Respiratory Vest System which is a prototype device, and because ABI also has an expert report concerning this case. In the trial paragraph, ABI anticipates that in the event of trial, the length of it will be 10 days. Electromed believes trial will only be 5 days.

5. **CLOSE OF DISCOVERY AND NONDISPOSITIVE MOTIONS**

The parties propose that the deadline for completing all depositions (excluding experts), responding to all discovery requests, and all document production, shall be completed (not served, but completed) on November 15, 2001. The parties further propose that the deadline for bringing nondispositive motions be November 15, 2001. Expect depositions will be completed by March 15, 2002.

6. **DISPOSITIVE MOTIONS AND TRIAL**

a. All dispositive motions shall be filed, served and heard on or before April 1, 2002.

b. This case will ready for trial on July 3, 2002.

c. At this time, the parties expect to each call 3-4 expert witnesses.

d. ABI believes that trial time will be 10 days, while Electromed believes it will be 5 days.

Respectfully submitted,

OPPENHEIMER WOLFF & DONNELLY LLP

By________________________

Cyrus A. Morton, #287325
David McKinley, #295814
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, Minnesota 55402-1609
Telephone: (612) 607-7000
Facsimile: (612) 607-7100

Attorneys for Plaintiff American Biosystems, Inc.

BARTZ & BARTZ PA

By________________________

Richard O. Bartz, #5174
Richard J. Bartz, #166364
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435-1983
Telephone: (952) 920-3959
Facsimile: (952) 920-6494

Attorneys for Defendant Electromed, Inc.

LOCAL RULES
FOR THE
UNITED STATES DISTRICT COURT
FOR THE
NORTHERN DISTRICT OF CALIFORNIA

Effective September 1, 1995

Including Amendments Received Through
March 1, 1999

Research Note

Use WESTLAW ® *to find cases citing a rule. In addition, use* WESTLAW *to search for specific terms, or to update a rule: see the CA-RULES and CA-ORDERS Scope Screens for further information.*

Amendments to these rules are published, as received, in the California Reporter 2d *advance sheets.*

Table of Rules

Preamble.

CIVIL LOCAL RULES

RULE 1. SCOPE AND PURPOSE OF RULES

Rule
1-1. Title.
1-2. Scope, Purpose and Construction.
(a) Scope.
(b) Supplement to Federal Rules.
1-3. Effective Date.
1-4. Sanctions and Penalties for Noncompliance.
1-5. Definitions.
(a) Clerk.
(b) Court.
(c) Day.
(d) File.
(e) FRCivP.
(f) FRCrimP.
(g) FRAppP.
(h) Federal Rule.
(i) General Orders.

EXHIBIT A

(e) Production of Voluminous Documents.

(1) A party producing 100 or fewer pages of documents pursuant to Civil L.R. 16–5, shall produce the original documents and present them for inspection and copying by the other parties or may make copies and provide them to the other parties.

(2) A party whose production pursuant to Civil L.R. 16–5(b) would include more than 100 pages of documents shall, no fewer than 7 days before such production, so notify the other parties. Each party to whom the production would be made may elect to:

(A) Inspect the documents to identify those it will arrange to have copied; or

(B) Request the disclosing party to copy and forward only specified categories of the documents; or

(C) Request the disclosing party to copy and forward all of the documents.

(3) A party copying documents at the request of another party under Civil L.R. 16–5(e)(1) or (2) shall be entitled to immediate reimbursement from the receiving parties at a reasonable rate. A party's request for copies of fewer than all of the documents subject to production under Civil L.R. 16–5 does not waive that party's right subsequently to inspect and obtain copies of the remaining documents without the need for a formal request pursuant to FRCivP 34.

(f) Parties Served or Added Before the Initial Conference. Any party added and served or which joins the action before the Case Management Conference shall comply with the pretrial schedule served with the complaint. For good cause, such party may file a motion for relief from the case management schedule pursuant to Civil L.R. 16–2(e).

(g) Parties Served or Added After the Initial Conference. When a party is added and served or joins in the case after the initial Case Management Conference, that party shall be subject to the schedules for disclosure and case management specified by the assigned judge's Case Management Order. For good cause, such party may file a motion for relief from the case management schedule pursuant to Civil L.R. 16–2(e).

(h) Privilege Log. In connection with disclosure or formal discovery of documentary materials, where a party withholds disclosure or production of documents on the ground of privilege, the parties may designate or the judge may direct an appropriate method for creating a log of such documents pursuant to FRCivP 26(b)(5).

Eff. Sept. 1, 1995.

RULE 16–6. DISCLOSURES AND PRETRIAL PROCEEDINGS IN PATENT CASES

(a) Scope. In addition to complying with Civil L.R. 16–5 and FRCiv P 26, in all civil actions filed in this court which include a claim of patent infringement, or which seek a declaratory judgment that a patent is not infringed or is invalid, the parties shall also comply with the disclosure requirements and procedures set forth in Civil L.R. 16–6 through 16–11.

(b) Confidentiality. If any document or information produced under Civil L.R. 16–6—16–11, is deemed confidential by the producing party and if the court has not entered a protective order, until a protective order is issued by the court, the document shall be marked "confidential" by the disclosing party and disclosure of the confidential document or information shall be limited to each party's outside attorney of record. If a party is not represented by outside attorney, disclosure of the confidential document or information shall be limited to a designated "in-house" attorney. The attorney to whom disclosure of a confidential document or information is made under this local rule shall keep it confidential and use it only for purposes of litigating the case.

(c) **Certification and Admissibility of Initial Disclosures.** All statements, disclosures or charts filed or served in accordance with these local rules must be dated and signed by counsel of record. Counsel's signature shall constitute a certification that to the best of his or her knowledge, information and belief, formed after an inquiry that is reasonable under the circumstances, the information contained in the statement, disclosure or chart is complete and correct at the time it is made.

(d) **Duty to Supplement Disclosures.** Unless otherwise ordered by the court, disclosures or charts governed by these local rules are subject to the duty of supplementation of FRCivP 26(e).

(e) **Admissibility of Disclosures.** Unless otherwise ordered by the court, statements, disclosures or charts governed by this local rule shall be admissible as evidence during the course of the action.

Adopted, eff. July 1, 1997.

RULE 16–7. INITIAL DISCLOSURE OF ASSERTED CLAIMS AND PRIOR ART IN PATENT CASES

(a) **Initial Disclosure of Asserted Claims.** No later than 45 days after filing a pleading that includes a claim for patent infringement, the party claiming patent infringement, except in those cases described in Civil L.R. 16–8, must serve on all parties an "Initial Disclosure of Asserted Claims" in conformity with Civil L.R. 16–7(b) and must produce or make available for inspection and copying the documents described in Civil L.R. 16–7(c).

(b) **Content of Initial Disclosure of Asserted Claims.** Separately for each opposing party, the "Initial Disclosure of Asserted Claims," shall contain the following information:

(1) Each claim of each patent in suit that is allegedly infringed by each opposing party;

(2) Separately for each allegedly infringed claim, each accused apparatus, product, device, process, method, act or other instrumentality ("accused instrumentality") of each opposing party of which the party is aware. This identification shall be as specific as possible. Each product, device and apparatus must be identified by name or model number, if known. Each method or process must be identified by name, if known, or by any product, device or apparatus which, when used, results in the practice of the claimed method or process;

(3) The date of conception and the date of reduction to practice of each asserted claim.

(c) **Document Production Accompanying Initial Disclosure of Asserted Claims.** At the time of filing the "Initial Disclosure of Asserted Claims," the party claiming patent infringement must produce to each opposing party or make available for inspection and copying all documents relating to:

(1) Any offers to sell each claimed invention prior to the date of application for the patent; and

(2) Research, design, and development of each claimed invention.

(d) **Initial Disclosure of Prior Art.** No later than 55 days after service upon it of an "Initial Disclosure Of Asserted Claims," each opposing party shall serve on all parties an "Initial Disclosure Of Prior Art" which conforms to Civil L.R. 16–7(e) and must produce or make available for inspection and copying the documents described Civil L.R. 16–7(f).

(e) **Content of Initial Disclosure of Prior Art.** The Initial Disclosure of Prior Art shall contain the following information:

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	Case Number: 00-2646 DWF/SRN **PLAINTIFF AMERICAN BIOSYSTEMS, INC.'S NOTICE OF MOTION AND MOTION TO AMEND COMPLAINT** **ORAL ARGUMENT REQUESTED**

TO: Defendant above-named and their attorney, R. John Bartz, Bartz & Bartz, Southdale Office Centre, 6750 France Avenue South, Suite 350, Edina, Minnesota 55435

NOTICE OF MOTION

PLEASE TAKE NOTICE that, pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, Plaintiff American Biosystems ("ABI"), by and through its counsel, will bring the following motion to Amend the Complaint before the Honorable Susan R. Nelson, Magistrate Judge of United States District Court, at 11:30 a.m. on May 31, 2001 in Courtroom 230, U.S. District Court, 316 North Robert Street, St. Paul, Minnesota 55101.

MOTION

Pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, ABI hereby moves the Court for leave to amend the Complaint to add a count for infringement of U.S. Patent No. 4,838,263 ("the '263 Patent") against Electomed. This motion is made on the basis of the points and authorities set forth in Plaintiff's Memorandum in Support of Plaintiff American Biosystems' Motion to Amend the Complaint and all the files, records, affidavits and

proceedings herein. Pursuant to Local Rule 15.1 a copy of the proposed Amended Complaint is attached hereto.

Dated: May 17, 2001

OPPENHEIMER WOLFF & DONNELLY LLP

By______________________________
Edward M. Laine, #59535
Cyrus A. Morton, #287325
3300 Plaza VII Building
45 South Seventh Street
Minneapolis, Minnesota 55402
Telephone: (612) 607-7000
Facsimile: (612) 607-7100

ATTORNEYS FOR PLAINTIFF AMERICAN BIOSYSTEMS, INC.

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	Case Number: 00-2646 DWF/SRN **PLAINTIFF AMERICAN BIOSYSTEMS' MEMORANDUM IN SUPPORT OF MOTION TO AMEND THE COMPLAINT** **ORAL ARGUMENT REQUESTED**

INTRODUCTION

Plaintiff American Biosystems, Inc. ("ABI") brings the present motion to amend the Complaint to add a count for infringement of U.S. Patent No. 4,838,263 ("the '263 Patent") against Electromed, Inc.("Electromed"). As required by Local Rule 15.1, the proposed amended complaint, including the '263 Patent, is attached to ABI's Notice and Motion. As alleged in paragraph 9 of the amended complaint, ABI is the exclusive licensee of the '263 Patent and possesses the right to sue. Subsequent to the filing of this lawsuit, ABI discovered that the '263 Patent is being infringed by Electromed. Accordingly, ABI sought a stipulation to amend the complaint from Electromed. The stipulation was sought in a timely fashion after discovery of infringement early in the lawsuit, and well before the October 1, 2001 deadline to amend the pleadings. Moreover, it is clear that ABI has the right to sue on the patent and has stated a claim for which relief can be granted in the amended complaint. Nevertheless, Electromed has refused to stipulate to the amendment and has instead embarked on a letter writing campaign containing various substantive arguments that the '263 Patent is not infringed nor invalid. Because ABI

believes that Electromed's arguments are meritless and that an agreement cannot be reached, ABI has filed the present motion.

I. ABI HAS DILIGENTLY SOUGHT A STIPULATION TO AMEND THE COMPLAINT

On April 3, 2001, ABI sent its first letter to Electromed requesting stipulation for leave to amend the complaint to add a count of infringement of the '263 Patent. As pointed out in the letter, the '263 Patent is owned by the University of Minnesota and ABI is the exclusive licensee. *See* Exhibit 1 to the Affidavit of David J. McKinley ("McKinley Aff."). Electromed responded on April 9, 2001 seeking a copy of the license agreement and that ABI produce a claim chart comparing claim 1 of the '263 Patent to Electromed's device, the Medpulse 2000. *See* McKinley Aff. Ex. 2. ABI responded on April 11, 2001 by producing the license agreement, pointing out that the complaint satisfies the Rules, and noting that the deadline for motions to amend is not until October 1, 2001. *See* McKinley Aff. Ex. 3. Page 13 of the License Agreement contains ABI's right to sue.

Electromed subsequently provided letters purporting to argue points concerning infringement and validity. *See* McKinley Aff. Exs. 4, 6 and 8. With the hope of resolving this amendment issue through stipulation, ABI responded to Electromed's arguments. *See* McKinley Aff. Exs. 5 and 7. However, it eventually became clear that an agreement could not be reached. Indeed, it is clear that Electromed has no intention to stipulate.

II. LIBERAL STANDARDS GOVERN A MOTION TO AMEND

Rule 15(a) of the Federal Rules of Civil Procedure provides, in pertinent part:

> A party may amend the party's pleading once, as a matter of course at any time before a responsive pleading is served . . . Otherwise, a party may amend the party's pleading only by leave of court or by written consent of the adverse party; *and leave shall be freely given when justice so requires.*

(Emphasis added). According to the Supreme Court, "this mandate is to be heeded." *Foman v. Davis*, 371 U.S. 178, 182, 83 S.Ct. 227, 230 (1962). Decisions on the merits are not to be avoided on mere technicalities. *Id.* at 181. Absent undue delay, bad faith by the movant, repeated failure to cure deficiencies by previous amendments, undue prejudice to the non-movant or futility of the amendment, leave to amend should be "freely given." *Id.* at 182.

Here, the amendment is sought early in the litigation and the deadline for pleading amendments is still some five months away. Moreover, while Electromed's letters appear to argue futility, no showing of futility can be made.

III. THE PROPOSED AMENDMENT STATES A CLAIM FOR PATENT INFRINGEMENT AND FUTILITY CANNOT BE SHOWN

On the question of futility, *Wright, Miller and Kane, Federal Practice and Procedure*, 2d. Ed. Volume VII, Section 1487 notes that if courts have considered the merits of the claim in ruling on a motion to amend, it has been in the context of whether the "complaint as amended could not withstand a motion to dismiss or whether the plaintiff has had sufficient opportunity to state a claim but has failed to do so." pp. 643-45. As ABI has pointed out in the correspondence, the proposed amendment to add a count of infringement of the '263 Patent clearly states a claim on which relief can be granted. The claim could easily withstand a motion to dismiss.

Electromed has not disputed that the proposed amended complaint states a claim for infringement of the '263 Patent by Electromed's Medpulse 2000. Instead, it has attempted to argue the ultimate merits of the claim. Electromed's arguments, which ABI believes will be shown to be baseless at a later dispositive motion or trial, certainly do not demonstrate futility.

A. Claim 1 of the '263 Patent reads on Electromed's Medpulse 2000.

A patent infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing

the properly construed claims to the device accused of infringing. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 Fed. Cir. 1995 (in banc), *aff.'d* 517 U.S. 370 1996. An infringement analysis involving a means-plus function limitation under 35 U.S.C. § 112, ¶ 6, which claim 1 of the '263 Patent invokes, is somewhat more involved. Generally, the overall structure in the patent specification that corresponds to the claimed functions must be identified and compared with the accused structures in order to determine infringement. *See Odetics, Inc. v. Storage Technology Corp.*, 185 F.3d 1259, 1268 Fed. Cir. 1999.

While Fed. R. Civ. P. 15 standards do not require a complete and final claim construction analysis under 35 U.S.C. § 112, ¶ 6 or a final application of the properly construed claims to the Electromed Medpulse 2000 device, ABI can show that a prima facie case exists. In that regard, ABI has prepared a preliminary claim chart. That analysis, including the claim language broken down into elements, where the structure corresponding to the function in the claims can be found in the specification, and where that structure can be found in the accused device along with pictures of the device, is attached as Exhibit 9 to the McKinley Affidavit. Essentially, claim 1 of the '263 Patent requires a bladder, a bellows, a vent, and a control. Those elements are found in the Medpulse 2000. Electromed's arguments to the contrary at most amount to genuine issues regarding claim construction that are well beyond the scope of this present motion. Accordingly, ABI has brought forth sufficient evidence to show that its claim of infringement of the '263 Patent is not futile.

B. The '263 Patent is Presumed Valid.

Under 35 U.S.C. § 282, all issued patents are presumed valid and the burden is on the challenger to prove invalidity by clear and convincing evidence. *See Hughes Tool Co. v. Dresser Indus., Inc.*, 816 F.2d 1549, 1555 (Fed. Cir. 1986). Accordingly, a validity challenge on the pleadings is inappropriate. Moreover, Electromed's asserted position of invalidity involves a

patent granted in 1933 covering a body massager not an oscillatory chest compression apparatus. As pointed out in the correspondence, the '652 Patent does not even include the first limitation of claim 1, a bladder. *See* McKinley Aff. Ex. 7. As such, Electromed's produced evidence is not even remotely clear and convincing on the question of validity and is not relevant to the allegation of infringement in the proposed amendment.

CONCLUSION

Given that ABI is the exclusive licensee of the '263 Patent, the proposed amended complaint states a claim for infringement of that patent by Electromed, and the fact that ABI has more than shown that the assertion of the '263 Patent is not futile, the present motion should be granted.

Respectfully submitted,

Dated: May 17, 2001

OPPENHEIMER WOLFF & DONNELLY LLP

Edward M. Laine, #59535
Cyrus A. Morton, #287325
David J. McKinley, #42867
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, Minnesota 55402-1609
Telephone: (612) 607-7000
Facsimile: (612) 607-7100

ATTORNEYS FOR PLAINTIFF AMERICAN BIOSYSTEMS, INC.

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	Case Number: 00-2646 DWF/SRN **PLAINTIFF AMERICAN BIOSYSTEMS' MEMORANDUM IN SUPPORT OF MOTION TO AMEND THE COMPLAINT** **ORAL ARGUMENT REQUESTED**

INTRODUCTION

Plaintiff American Biosystems, Inc. ("ABI") brings the present motion to amend the Complaint to add a count for infringement of U.S. Patent No. 4,838,263 ("the '263 Patent") against Electromed, Inc.("Electromed"). As required by Local Rule 15.1, the proposed amended complaint, including the '263 Patent, is attached to ABI's Notice and Motion. As alleged in paragraph 9 of the amended complaint, ABI is the exclusive licensee of the '263 Patent and possesses the right to sue. Subsequent to the filing of this lawsuit, ABI discovered that the '263 Patent is being infringed by Electromed. Accordingly, ABI sought a stipulation to amend the complaint from Electromed. The stipulation was sought in a timely fashion after discovery of infringement early in the lawsuit, and well before the October 1, 2001 deadline to amend the pleadings. Moreover, it is clear that ABI has the right to sue on the patent and has stated a claim for which relief can be granted in the amended complaint. Nevertheless. Electromed has refused to stipulate to the amendment and has instead embarked on a letter writing campaign containing various substantive arguments that the '263 Patent is not infringed nor invalid. Because ABI

believes that Electromed's arguments are meritless and that an agreement cannot be reached, ABI has filed the present motion.

I. ABI HAS DILIGENTLY SOUGHT A STIPULATION TO AMEND THE COMPLAINT

On April 3, 2001, ABI sent its first letter to Electromed requesting stipulation for leave to amend the complaint to add a count of infringement of the '263 Patent. As pointed out in the letter, the '263 Patent is owned by the University of Minnesota and ABI is the exclusive licensee. *See* Exhibit 1 to the Affidavit of David J. McKinley ("McKinley Aff."). Electromed responded on April 9, 2001 seeking a copy of the license agreement and that ABI produce a claim chart comparing claim 1 of the '263 Patent to Electromed's device, the Medpulse 2000. *See* McKinley Aff. Ex. 2. ABI responded on April 11, 2001 by producing the license agreement, pointing out that the complaint satisfies the Rules, and noting that the deadline for motions to amend is not until October 1, 2001. *See* McKinley Aff. Ex. 3. Page 13 of the License Agreement contains ABI's right to sue.

Electromed subsequently provided letters purporting to argue points concerning infringement and validity. *See* McKinley Aff. Exs. 4, 6 and 8. With the hope of resolving this amendment issue through stipulation, ABI responded to Electromed's arguments. *See* McKinley Aff. Exs. 5 and 7. However, it eventually became clear that an agreement could not be reached. Indeed, it is clear that Electromed has no intention to stipulate.

II. LIBERAL STANDARDS GOVERN A MOTION TO AMEND

Rule 15(a) of the Federal Rules of Civil Procedure provides, in pertinent part:

> A party may amend the party's pleading once, as a matter of course at any time before a responsive pleading is served . . . Otherwise, a party may amend the party's pleading only by leave of court or by written consent of the adverse party; *and leave shall be freely given when justice so requires.*

(Emphasis added). According to the Supreme Court, "this mandate is to be heeded." *Foman v. Davis*, 371 U.S. 178, 182, 83 S.Ct. 227, 230 (1962). Decisions on the merits are not to be avoided on mere technicalities. *Id.* at 181. Absent undue delay, bad faith by the movant, repeated failure to cure deficiencies by previous amendments, undue prejudice to the non-movant or futility of the amendment, leave to amend should be "freely given." *Id.* at 182.

Here, the amendment is sought early in the litigation and the deadline for pleading amendments is still some five months away. Moreover, while Electromed's letters appear to argue futility, no showing of futility can be made.

III. THE PROPOSED AMENDMENT STATES A CLAIM FOR PATENT INFRINGEMENT AND FUTILITY CANNOT BE SHOWN

On the question of futility, *Wright, Miller and Kane, Federal Practice and Procedure*, 2d. Ed. Volume VII, Section 1487 notes that if courts have considered the merits of the claim in ruling on a motion to amend, it has been in the context of whether the "complaint as amended could not withstand a motion to dismiss or whether the plaintiff has had sufficient opportunity to state a claim but has failed to do so." pp. 643-45. As ABI has pointed out in the correspondence, the proposed amendment to add a count of infringement of the '263 Patent clearly states a claim on which relief can be granted. The claim could easily withstand a motion to dismiss.

Electromed has not disputed that the proposed amended complaint states a claim for infringement of the '263 Patent by Electromed's Medpulse 2000. Instead, it has attempted to argue the ultimate merits of the claim. Electromed's arguments, which ABI believes will be shown to be baseless at a later dispositive motion or trial, certainly do not demonstrate futility.

A. Claim 1 of the '263 Patent reads on Electromed's Medpulse 2000.

A patent infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing

the properly construed claims to the device accused of infringing. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 Fed. Cir. 1995 (in banc), *aff.'d* 517 U.S. 370 1996. An infringement analysis involving a means-plus function limitation under 35 U.S.C. § 112, ¶ 6, which claim 1 of the '263 Patent invokes, is somewhat more involved. Generally, the overall structure in the patent specification that corresponds to the claimed functions must be identified and compared with the accused structures in order to determine infringement. *See Odetics, Inc. v. Storage Technology Corp.*, 185 F.3d 1259, 1268 Fed. Cir. 1999.

While Fed. R. Civ. P. 15 standards do not require a complete and final claim construction analysis under 35 U.S.C. § 112, ¶ 6 or a final application of the properly construed claims to the Electromed Medpulse 2000 device, ABI can show that a prima facie case exists. In that regard, ABI has prepared a preliminary claim chart. That analysis, including the claim language broken down into elements, where the structure corresponding to the function in the claims can be found in the specification, and where that structure can be found in the accused device along with pictures of the device, is attached as Exhibit 9 to the McKinley Affidavit. Essentially, claim 1 of the '263 Patent requires a bladder, a bellows, a vent, and a control. Those elements are found in the Medpulse 2000. Electromed's arguments to the contrary at most amount to genuine issues regarding claim construction that are well beyond the scope of this present motion. Accordingly, ABI has brought forth sufficient evidence to show that its claim of infringement of the '263 Patent is not futile.

B. The '263 Patent is Presumed Valid.

Under 35 U.S.C. § 282, all issued patents are presumed valid and the burden is on the challenger to prove invalidity by clear and convincing evidence. *See Hughes Tool Co. v. Dresser Indus., Inc.*, 816 F.2d 1549, 1555 (Fed. Cir. 1986). Accordingly, a validity challenge on the pleadings is inappropriate. Moreover, Electromed's asserted position of invalidity involves a

patent granted in 1933 covering a body massager not an oscillatory chest compression apparatus. As pointed out in the correspondence, the '652 Patent does not even include the first limitation of claim 1, a bladder. *See* McKinley Aff. Ex. 7. As such, Electromed's produced evidence is not even remotely clear and convincing on the question of validity and is not relevant to the allegation of infringement in the proposed amendment.

CONCLUSION

Given that ABI is the exclusive licensee of the '263 Patent, the proposed amended complaint states a claim for infringement of that patent by Electromed, and the fact that ABI has more than shown that the assertion of the '263 Patent is not futile, the present motion should be granted.

Respectfully submitted,

Dated: May 17, 2001

OPPENHEIMER WOLFF & DONNELLY LLP

Edward M. Laine, #59535
Cyrus A. Morton, #287325
David J. McKinley, #42867
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, Minnesota 55402-1609
Telephone: (612) 607-7000
Facsimile: (612) 607-7100

ATTORNEYS FOR PLAINTIFF AMERICAN BIOSYSTEMS, INC.

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	Case Number: 00-2646 DWF/SRN **AFFIDAVIT OF DAVID J. MCKINLEY**

DAVID J. MCKINLEY, being first duly sworn, upon oath, deposes and states as follows:

1. I am an attorney at Oppenheimer Wolff & Donnelly LLP and am one of the attorneys representing American Biosystems, Inc. ("ABI") with respect to the above matter. I am admitted to practice before the United States Patent and Trademark Office. Attached hereto are ten Exhibits, each identified below.

2. Exhibit 1 is a true and correct copy of correspondence dated April 3, 2001 from Cyrus A. Morton to Richard O. Bartz enclosing the Amended Complaint for Patent Infringement.

3. Exhibit 2 is a true and correct copy correspondence dated April 9, 2001 from Richard O. Bartz to Cyrus A. Morton.

4. Exhibit 3 is a true and correct copy of correspondence dated April 11, 2001 from Cyrus A. Morton to Richard O. Bartz.

5. Exhibit 4 is a true and correct copy of correspondence dated April 17, 2001 from Richard O. Bartz to Cyrus A. Morton.

6. Exhibit 5 is a true and correct copy of correspondence dated April 24, 2001 from Cyrus A. Morton to Richard O. Bartz.

7. Exhibit 6 is a true and correct copy of correspondence dated April 23, 2001 from Richard O. Bartz to Cyrus A. Morton.

8. Exhibit 7 is a true and correct copy of correspondence dated April 27, 2001 from David J. McKinley to Richard O. Bartz.

9. Exhibit 8 is a true and correct copy of correspondence dated April 30, 2001 from Richard O. Bartz to Cyrus A. Morton.

10. Exhibit 9 is a Preliminary Claim Chart I prepared documenting United States patent 4,838,263 and the Electromed Medpulse 2000 device.

FURTHER AFFIANT SAITH NOT.

David J. McKinley

Subscribed and sworn to before me
this 17th day of May, 2001.

Notary Public

SHARON L. OWEN
NOTARY PUBLIC – MINNESOTA
My Comm. Expires Jan. 31, 2005

OPPENHEIMER

OPPENHEIMER WOLFF & DONNELLY LLP

VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402-1609

612.607.7000
Fax 612.607.7100

Direct Dial: 612.607.7354
E-Mail: C Morton@oppenheimer.com

April 3, 2001

Richard O. Bartz, Esq.
Bartz & Bartz
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435

Re: American Biosystems, Inc. v. Electromed, Inc.
Court File Number: 00-2646 DWF/SRN
Our File No.: 12653/13

Dear Mr. Bartz:

Enclosed please find a Stipulation and Order for Leave to Amend Complaint and an Amended Complaint. As you can see, the Complaint has been added to assert infringement of an additional patent, namely the '263 Patent which is owned by the University of Minnesota and of which American Biosystems, Inc. is the exclusive licensee. If you would like to discuss this amendment, please give me a call, otherwise please sign the attached Stipulation and return it to me so that we may file the Amended Complaint with the Court.

Sincerely,

Cyrus A. Morton

CAM:slo
Enclosures

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	Case Number: 00-2646 DWF/SRN **STIPULATION AND ORDER FOR LEAVE TO AMEND COMPLAINT**

Pursuant to Fed. R. Civ. P. 15(a), the parties, through their respective undersigned attorneys, hereby stipulate and agree that the Complaint may be amended as attached and specifically to allege infringement of United States Patent No. 4,838,263 by Electromed.

Date: April ___, 2001

OPPENHEIMER WOLFF & DONNELLY LLP

By_____
Edward M. Laine, #59535
Cyrus A. Morton, #287325
David J. McKinley, #295814
3400 Plaza VII Building
45 South 7th Street
Minneapolis, MN 55402
Phone: (612) 607-7000
Fax No.: (612) 607-7100

ATTORNEYS FOR PLAINTIFF

Dated: April ____, 2001

BARTZ & BARTZ

By _____
Richard O. Bartz, #5174
R. John Bartz, #166364
Southdale Office Centre
6750 France Avenue South
Suite 350
Edina, MN 55435
Telephone: (612) 920-3959
Facsimile: (612) 920-6494

ATTORNEYS FOR DEFENDANT

ORDER

Pursuant to the Stipulation of the parties, it is hereby Ordered that Plaintiff may amend its Complaint as stipulated.

Dated: _____, 2001

_____
Susan R. Nelson
United States Magistrate Judge

Law Offices
BARTZ & BARTZ
A Professional Association

Mary A. Bartz
R. John Bartz
Richard O. Bartz

Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435

Tel.: (952) 920-3959
Fax: (952) 920-6494
E-Mail: bartzpa@mcleodusa.net

April 9, 2001

Mr. Cyrus A. Morton
Oppenheimer Wolff & Donnelly LLP
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402

RE: American Biosystems, Inc. v. Electromed, Inc.
File: E100.18.1 Your file: 12653/13

Dear Mr. Morton:

We have your letter of April 3, 2001 and the proposed amended complaint.

We ask that you send us a copy of the license agreement with the Regents of the University of Minnesota concerning Patent 4,838,263. There is no evidence that American Biosystems, Inc. has standing to include U.S. Patent 4,838,263 in this lawsuit.

Patent 4,838,263 has only one base claim (Claim 1). We do not find that the apparatus of Claim 1 is operable and includes the vest and pulsator of the Electromed Medpulse 2000 Respiratory Vest System. Enclosed is a claim chart of Claim 1. Please advise us how the Electromed Medpulse 2000 Respiratory Vest System is included in the elements A-D of Claim 1.

Very truly yours,

BARTZ & BARTZ, P.A.

Richard O. Bartz

Richard O. Bartz
Attorney at Law

ROB/sja

U.S. Patent 4,838,263

Claim 1	ELECTROMED MEDPULSE 2000 Respiratory Vest System
Oscillatory chest compression apparatus for a person, comprising:	
A. means for applying a force to the chest of said person, said force applying means including a bladder for receiving pressurized air;	A.
B. means for supplying a continuous regular pattern of pulses of said pressurized air to said bladder at a frequency irrespective of and greater than the breathing frequency of said person;	B.
C. means for venting said pressurized air from said bladder, and	C.
D. means for controlling said pressurized air in said bladder so that the pressure therein can be increased and decreased in correspondence with the expiration and inspiration breathing frequency of said person wherein said force is applied by said apply means at the pulse frequency of said supplying means with greater impact when said controlling means allows increase air pressure in said bladder and with lessor impact when said controlling means allows decreased air pressure in said bladder.	D.

OPPENHEIMER

OPPENHEIMER WOLFF & DONNELLY LLP

Brussels | Orange County
Geneva | Paris
Los Angeles | Silicon Valley
Minneapolis | Washington, D.C.
New York | oppenheimer.com

P TI, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402-1609

612.607.7000
Fax 612.607.7100

Direct Dial: 612.607.7354
E-Mail: C Morton@oppenheimer.com

April 11, 2001

VIA FACSIMILE
AND U.S. MAIL

Richard O. Bartz, Esq.
Bartz & Bartz
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435

Re: American Biosystems, Inc. v. Electromed, Inc.
Court File Number: 00-2646 DWF/SRN
Our File No.: 12653/13

Dear Mr. Bartz:

I have received your letter of April 9, 2001 regarding ABI's proposed Amended Complaint. I note that you would like to see evidence of ABI's standing to sue on U.S. Patent 4,838,263 and evidence of how the Electromed MedPulse 2000 respiratory vest system is included in the elements A through D of Claim 1. This evidence is not required to satisfy the notice pleading standards under the Federal Rules of Civil Procedure. You are free to request a copy of the License Agreement through normal discovery as you are free to attempt to discover our infringement position. These activities normally occur after a suit is filed, or in this case, after the complaint is amended. Additionally, it is very early in this case and the deadline for motions to amend the pleadings is not until October 1, 2001.

Nevertheless, in the interest of cooperation, I have included a courtesy copy of the License Agreement with the Regents of the University of Minnesota. However, we will not construe the claims and produce a claim chart in order to get your agreement to a simple amendment to the complaint, particularly when you have no basis to oppose the amendment. Accordingly, I ask you again to sign the Stipulation to amend the complaint and return it to me or inform me that I will need to enlist the Court's assistance.

Sincerely,

Cyrus A. Morton

CAM:slo
Enclosure

CONFIDENTIAL COPY

M&G-3509.11-US-LB

U of M:

Ref: L:49/PO3:29/A

AS: 880822

Rev. CCS-881014

LICENSE AGREEMENT

THIS AGREEMENT is effective upon the 2nd day of Nov., 1988.

American Biosystems, Inc. (hereafter COMPANY), a corporation of the State of Minnesota, that has a principal place of business at 750 Walnut Street, Marine on St. Croix, Minnesota 55047, and the Regents of the University of Minnesota (hereafter UNIVERSITY), a non-profit corporation of the State of Minnesota, that has a principal office at 100 Church Street SE, Minneapolis, Minnesota, agree as follows:

ARTICLE I

INTRODUCTION

1.1 COMPANY and the UNIVERSITY are occasionally referred to as "parties" in singular or plural usage as indicated by the context.

1.2 Terms in this agreement which appear in upper case letters, other than the names of the parties, NEWCO, and article headings, have the meanings given in Article II.

1.3 The UNIVERSITY, through the efforts of Dr. Warren Warwick and Leland Hansen, has developed a device and method to assist a person (especially a person with cystic fibrosis) in the expulsion of mucus that has accumulated in the lungs. The

UNIVERSITY has filed U.S. and foreign applications on this invention. The UNIVERSITY desires to enter into a license arrangement with a company that will commercialize this invention and that will fund additional UNIVERSITY research concerning the invention, including research to develop other therapeutic and diagnostic applications.

1.4 COMPANY is interested in obtaining exclusive commercial rights to the invention and in cooperating with the UNIVERSITY in further research concerning the invention. Subject to various factors now under review, COMPANY may sublicense the commercial rights it obtains to a new company (hereafter NEWCO) that is being formed to commercialize this invention as its first development project. NEWCO is also intended to commercialize other medical device products acquired from other sources.

1.5 The UNIVERSITY and COMPANY agree to the following terms and conditions in order to effect the purposes given above.

ARTICLE II

DEFINITIONS

2.1 TECHNOLOGY shall mean all information, knowledge, know-how, and inventions, whether patentable or not, in the possession of the UNIVERSITY as of the date of this agreement that were developed by or under the supervision of Dr. Warren Warwick and/or Leland Hansen of the UNIVERSITY concerning percussive or compressive thoracic physiotherapy devices (both therapeutic and diagnostic) and related methods, systems and

instrumentation, and specifically including the chest compression device which is the subject of U.S. Patent Application Number 045,888, filed May 1, 1987 (U of M docket 86005).

2.2 UNIVERSITY IMPROVEMENTS shall mean all improvements and developments specifically related to the TECHNOLOGY, whether patentable or not, that are made by or under the supervision of Dr. Warren Warwick and/or Leland Hansen within the first five (5) years following the date of this agreement and all improvements and developments of any kind, whether patentable or not, that are made by any UNIVERSITY employee at any time under funding from COMPANY. UNIVERSITY IMPROVEMENTS shall not include any improvements or developments made by either Dr. Warren Warwick or Leland Hansen after ceasing to be an employee of the UNIVERSITY. Dr. Warren Warwick and Leland Hansen agree to assign all UNIVERSITY IMPROVEMENTS to the UNIVERSITY.

2.3 COMPANY IMPROVEMENTS shall mean all improvements and developments specifically related to the TECHNOLOGY, whether patentable or not, that are made by COMPANY at any time.

2.4 U.S. APPLICATIONS shall mean U.S. Patent Application Number 045,888 ("Chest Compression Apparatus"), filed May 1, 1987, and all other present and future U.S. patent applications, including continuations, divisionals, and applications for reissue, on the TECHNOLOGY and UNIVERSITY IMPROVEMENTS (but not on COMPANY IMPROVEMENTS).

2.5 FOREIGN APPLICATIONS shall mean International Application No. PCT/US88/01342 ("Chest Compression Apparatus"), filed April 26, 1988, corresponding to U.S. Application No. 045,888 and designating the European Patent Office (all available states), Denmark, Finland, Japan, and Norway, and shall mean all other present and future foreign patent applications on the TECHNOLOGY and UNIVERSITY IMPROVEMENTS (but not on COMPANY IMPROVEMENTS).

2.6 U.S. PATENTS shall mean all U.S. patents and reissues that issue on U.S. APPLICATIONS.

2.7 FOREIGN PATENTS shall mean all foreign patents issuing on FOREIGN APPLICATIONS.

2.8 APPLICATIONS shall mean U.S. APPLICATIONS and FOREIGN APPLICATIONS.

2.9 PATENTS shall mean U.S. PATENTS and FOREIGN PATENTS.

2.10 PRODUCTS shall mean all products that incorporate the TECHNOLOGY and/or UNIVERSITY IMPROVEMENTS.

2.11 SUBLICENSEES shall mean sublicensees of COMPANY under this agreement.

ARTICLE III

APPLICATIONS AND PATENTS

3.1 The UNIVERSITY agrees to use its best efforts, consistent with sound and reasonable judgment, to continue to prosecute U.S. Application No. 045,888 and to maintain any U.S. PATENT issuing from that APPLICATION. The UNIVERSITY agrees to

use its best efforts, consistent with sound and reasonable judgment, to timely file and prosecute other U.S. APPLICATIONS and maintain other U.S. PATENTS as requested by COMPANY. The UNIVERSITY shall have the option, at its sole discretion and expense, to file and prosecute U.S. APPLICATIONS and maintain U.S. PATENTS that COMPANY has determined not to pursue.

3.2 The UNIVERSITY agrees to use its best efforts, consistent with sound and reasonable judgment, to timely file and prosecute FOREIGN APPLICATIONS and maintain FOREIGN PATENTS in countries requested by COMPANY. The UNIVERSITY shall have the option, at its sole discretion and expense, to file and prosecute FOREIGN APPLICATIONS and to maintain FOREIGN PATENTS in countries not requested by COMPANY.

3.3 The UNIVERSITY shall have sole title to the TECHNOLOGY and UNIVERSITY IMPROVEMENTS and to all APPLICATIONS and PATENTS.

3.4 The UNIVERSITY shall bear all expenses for filing and prosecuting U.S. Application No. 045,888, and maintaining any U.S. PATENTS issuing on that APPLICATION. COMPANY shall reimburse the UNIVERSITY for all future out-of-pocket expenses from filing and prosecuting any additional U.S. APPLICATIONS and all FOREIGN APPLICATIONS and maintaining any additional U.S. and all FOREIGN PATENTS, requested by COMPANY. COMPANY, at UNIVERSITY'S request, shall also reimburse the UNIVERSITY for its agreed upon pro-rata share of filing the PCT application corresponding to U.S. Application No. 045,888. COMPANY may

credit such reimbursements for expenses relating to a particular country against royalties owed to the UNIVERSITY for sales of PRODUCTS in that country. COMPANY may, at any time terminate its obligation to reimburse the UNIVERSITY for expenses relating to a particular APPLICATION or PATENT by giving written notice to the UNIVERSITY. COMPANY shall not be liable for any expenses relating to that APPLICATION or PATENT that are incurred after that notice. The UNIVERSITY shall thereafter have sole right to prosecute or maintain such APPLICATION or PATENT at its own expense. 3.5 The UNIVERSITY shall direct and administer the prosecution of APPLICATIONS and of PATENTS. However, the UNIVERSITY shall keep COMPANY informed of its filing and prosecution activities, and shall give COMPANY the opportunity to comment on major decisions and actions concerning such activities. COMPANY agrees to fully cooperate with the UNIVERSITY in filing and prosecuting APPLICATIONS.

3.6 Nothing in this agreement shall be construed to give COMPANY rights in any technologies developed by the UNIVERSITY other than those explicitly specified in this agreement. Nothing in this agreement shall be construed to give the UNIVERSITY rights in technologies developed by COMPANY other than those explicitly specified in this agreement.

3.7 In the event that after December 31, 1993, the UNIVERSITY has a bona fide opportunity to license any FOREIGN PATENT or FOREIGN APPLICATION, it shall notify COMPANY in writing

of the patent or application, the country involved, and the name of the prospective licensee, and COMPANY shall thereafter have ninety (90) days to demonstrate that it is or is about to market PRODUCTS in such country or has sublicensed its rights to such country. If COMPANY fails to do so, the UNIVERSITY shall be free to license such rights in such country and the COMPANY'S rights in such country to the licensed FOREIGN PATENT or FOREIGN APPLICATION shall cease.

ARTICLE IV

LICENSE GRANT AND COMMERCIAL EFFORTS

4.1 Subject to the terms and conditions of this agreement, the UNIVERSITY hereby grants and COMPANY hereby accepts an exclusive worldwide license to practice the TECHNOLOGY and UNIVERSITY IMPROVEMENTS to make, have made, use, and sell, lease, or otherwise dispose of PRODUCTS. This license shall be effective under all U.S. and FOREIGN APPLICATIONS and PATENTS. This license includes the right to grant sublicenses, as provided in 4.2. As one term of COMPANY's sublicense to NEWCO (if any is granted), COMPANY shall require NEWCO to issue stock to the UNIVERSITY in the amount of one percent (1%) of the initial issue of shares of NEWCO. The UNIVERSITY retains an irrevocable, nonexclusive and nontransferable right to practice for its own non-commercial educational and research purposes (including support of existing patient-user population), the TECHNOLOGY and UNIVERSITY IMPROVEMENTS.

4.2 The license granted by this agreement is to COMPANY alone and does not grant any rights to third parties or to any subsidiary or affiliate of COMPANY. However, COMPANY may transfer this agreement by way of sale of COMPANY, through sale of assets and/or sale of stock, provided that such sale is not primarily for the benefit of creditors, and further provided that the UNIVERSITY has advance notice of such a sale and that the UNIVERSITY is given the opportunity to review and comment on the purchaser. COMPANY shall also have the right to grant sublicenses under this agreement. The COMPANY shall give the UNIVERSITY an opportunity to review and comment on any sublicense prior to its execution. If COMPANY fails to give the UNIVERSITY the opportunity to review and comment on a sublicense agreement or a sale of COMPANY, the UNIVERSITY shall have the right to require that the sublicense or transfer of this agreement be suspended pending review and comment by the UNIVERSITY and the COMPANY shall retain the right to terminate or void such sublicense or transfer in response to the UNIVERSITY'S comments. COMPANY shall be responsible to the UNIVERSITY for the payment of royalties received by COMPANY on sales, leases, and other dispositions of PRODUCTS by SUBLICENSEES. If any sublicensee fails to pay royalties when due, and fails to cure the breach within sixty (60) days of written notice, COMPANY shall terminate the sublicense to the maximum extent permitted by law.

4.3 COMPANY shall use its best efforts, consistent with its sound and reasonable business practices and judgment and its size and staffing, to effect commercial sales of PRODUCTS as soon as practicable and to maximize these sales. "Best efforts" under this clause shall mean satisfying the following milestones in the times indicated:

Milestone		Months
(a)	design of first PRODUCT	first 6 months
(b)	testing filing for regulatory approval, and pre-clinical evaluation	next 18 months
(c)	establish marketing and distribution network	next 6 months

Beginning in April 1989 and continuing until commercial sales begin, COMPANY shall provide the UNIVERSITY with brief written reports of COMPANY's efforts and plans to effect commercialization. COMPANY shall provide these reports quarterly with the royalty report specified in 5.3.

4.5 COMPANY shall not use the name of the UNIVERSITY for commercial purposes without prior written approval from the UNIVERSITY.

4.6 COMPANY and SUBLICENSEES shall alone have the obligation to ensure that any PRODUCT they make, use, or sell, lease, or otherwise dispose of is not defective and that any PRODUCT satisfies all applicable government regulations, including FDA requirements.

4.7 COMPANY hereby grants the UNIVERSITY a nonexclusive, non-transferrable royalty-free right to use COMPANY IMPROVEMENTS for the UNIVERSITY's own non-commercial research and education purposes.

ARTICLE V

ROYALTIES, REPORTS AND RECORDS

5.1 For the license granted hereunder, COMPANY shall pay or cause to be paid to the UNIVERSITY a royalty of 3% on net sales of PRODUCT for treatment or diagnosis of cystic fibrosis and 4 1/2% on net sales of PRODUCT for any other purpose or share sublicensing income as hereinafter set forth, where such PRODUCT is manufactured, assembled, or sold, leased, or otherwise disposed of in a country where it is covered by any valid claim of the PATENTS or any pending claim of any U.S. APPLICATION or any corresponding claim of any FOREIGN APPLICATION. For purposes of determining whether a royalty is due, every claim of every PATENT and every claim of every pending patent APPLICATION shall be presumed valid unless or until: (a) it is held invalid in any proceedings before any court, arbitration, or patent office; or (b) is acknowledged by the UNIVERSITY to be invalid; or (c) is

contained within a patent application which has a priority filing date which is more than five (5) years old (regardless of whether or not the APPLICATION was filed as a convention or non-convention case). "Net sales" in this clause means the gross amount invoiced for sales, leases, and other dispositions of PRODUCT by COMPANY and SUBLICENSEES less (i) all trade, quantity, and cash discounts actually allowed, (ii) all credits and allowances actually granted on account of rejection, returns, billing errors, and retroactive price reductions, (iii) duties, freight and insurance, and (iv) excise, sale and use taxes, and equivalent taxes. Except as noted herein, the royalties of this Paragraph 5.1 shall apply to the COMPANY and all SUB-LICENSEES. As the only exceptions to the foregoing, if the COMPANY grants sublicenses under this Agreement to anyone other than NEWCO in a bona fide, arms length transaction, the royalties of this Paragraph 5.1 shall not apply, and, instead, any royalties or other cash payments received by the COMPANY for the sale of PRODUCT as described herein as a result of any such sublicense shall be shared between the COMPANY and the UNIVERSITY in the manner hereinafter set forth. The COMPANY shall be entitled to two-thirds of the payments received from such sublicensees and the UNIVERSITY shall be entitled to one-third of the payments received from the sublicensees.

5.2 Royalties shall be payable only once with respect to the same unit of PRODUCT. If any PATENT has not yet been held invalid, but is ineffective in preventing significant competition from similar products and that competition significantly reduces or otherwise restricts the COMPANY's market share or results in

the COMPANY reducing its selling price, then the royalties or sublicense fees set forth in Paragraph 5.1 shall be reduced by fifty percent (50%) on a country-by-country basis.

5.3 COMPANY shall provide the UNIVERSITY with quarterly written reports of all sales, leases, or other dispositions of PRODUCTS by COMPANY and SUBLICENSEES. The report shall be made within sixty (60) days of the end of each calendar quarter whether or not any sales of PRODUCTS has occurred during that quarter. The UNIVERSITY agrees to keep the information in these reports confidential, except as may be necessary to maintain an action against COMPANY for breach of this agreement. Royalty payments for sales, leases, and other dispositions of PRODUCTS invoiced during a calendar quarter shall accompany the report for that quarter. Payments shall be made in United States Dollars. Any currency translations that are necessary to calculate payments shall be made at the exchange rate used by COMPANY for financial accounting purposes in accordance with generally accepted accounting principles. Royalty checks shall be made payable to the Regents of the University of Minnesota and mailed to the address specified in Article XII.

5.4 COMPANY and SUBLICENSEES shall keep and maintain sufficient records of sales, leases, and other disposition of PRODUCT to enable verification of royalty payments in accordance with generally accepted accounting practices. Such records of the COMPANY shall be open to inspection upon at least ten (10)

days written notice, such inspection to be at reasonable times during normal business hours by a certified public accountant chosen by the UNIVERSITY and acceptable to COMPANY for the limited and sole purpose of verifying royalty payment. Such inspection shall be made at the UNIVERSITY's expense. The UNIVERSITY and the auditors agree to hold such records confidential, except as may be necessary to maintain an action against COMPANY for breach of this agreement. The records required by this paragraph shall be maintained and available for inspection for a period of five (5) years following the calendar quarter to which they pertain. This paragraph shall survive termination of this agreement.

ARTICLE VI

INFRINGEMENT

6.1 In the event that the UNIVERSITY or COMPANY determines that a third party is making, using or selling a product that may infringe a U.S. or FOREIGN PATENT, it will promptly notify the other party in writing. COMPANY may, at its sole option, bring suit against such alleged infringer in its name or the UNIVERSITY's name or in both names as may be required to establish jurisdiction. In the event COMPANY decides to bring suit, it shall give prompt written notice to the UNIVERSITY of that fact. All recoveries in such suit shall belong to COMPANY except that the UNIVERSITY shall have the right to elect to pay up to fifty percent (50%) of the litigation costs and receive a

percentage of any recovery equal to the percentage of litigation costs paid. The UNIVERSITY must make such election within thirty (30) days of its receipt of notice that COMPANY has decided to bring suit. The UNIVERSITY shall also have the right to choose to be represented by separate counsel in any such suit at its own expense. Such expense for separate counsel shall not be considered as part of "litigation costs" for purposes of determining the UNIVERSITY's share of any recovery in accordance with the sentence above. If COMPANY elects not to bring a suit against the alleged infringer, it shall promptly notify the UNIVERSITY of that fact and the UNIVERSITY shall have the right to commence such action at its own cost and expense, in which case any recoveries shall belong to the UNIVERSITY. In such suits by the UNIVERSITY, COMPANY shall have rights of participation and recovery that are the same as the UNIVERSITY's rights as provided above when COMPANY elects to sue.

6.2 If, to avoid infringement of a third party patent, the COMPANY or any of its sublicensees pays royalties to the third party to enable the COMPANY or such licensee to make, use or sell the PRODUCTS, the royalties paid by the COMPANY or its licensee to the third party may be used as a credit against the earned royalties or sublicense fees owed by the COMPANY to the UNIVERSITY. However, at no time may the credits be used for more than fifty percent (50%) of the earned royalty or other payments

owed the UNIVERSITY. If the credits are not completely used in any calendar year, then the unused credits may be carried forward to subsequent years.

ARTICLE VII

TERM AND TERMINATION

7.1 This agreement's term shall end at the later of: (a) when the last of all PATENTS has either expired or been invalidated in an unappealed decision by a court having jurisdiction; or (b) six (6) years from the date of this agreement. If no PATENT issues, this agreement's term shall end upon the date no APPLICATION remains pending or upon the date six (6) years following the effective date of this agreement, whichever occurs first. If this agreement terminates under this Paragraph 7.1, all rights of the COMPANY under Paragraph 4.1 shall continue in perpetuity.

7.2 The UNIVERSITY shall have the right to terminate this agreement upon sixty (60) days written notice by certified mail to COMPANY under the following circumstances unless the breach is cured by the COMPANY:

(1) if royalties due the UNIVERSITY are unpaid;

(2) if there is a material breach or default of this agreement by COMPANY;

(3) if COMPANY fails to use its best efforts to effect commercial sales of PRODUCT in accordance with 4.3; or

(4) if COMPANY fails to give the UNIVERSITY an opportunity to review and comment upon the sale of COMPANY or a sublicense of this agreement in accordance with 4.4.

If COMPANY does not cure a curable default within sixty (60) days of receipt of notice to termination, such termination shall become effective. If such termination is effective and NEWCO as a sublicensee is not in breach, the UNIVERSITY shall offer NEWCO the option to undertake this agreement in its entirety.

7.3 COMPANY may terminate the license granted hereunder at any time upon sixty (60) days notice by certified mail to the UNIVERSITY.

7.4 Upon end of term of this agreement in accordance with 7.1 above, COMPANY shall have the unrestricted royalty-free right to make, use and sell, lease or otherwise dispose of PRODUCTS anywhere in the world.

7.5 Upon termination of this agreement for any reason, including the end of term as specified above, all rights and obligations under this agreement shall terminate, except those that have accrued prior to termination (e.g., the obligation to report and pay royalty on sales made under this agreement) and except as specified in the agreement (see 5.4, 7.1, 7.2, 7.4 and 9.3).

ARTICLE VIII

PUBLICATION

8.1 It is the policy of the UNIVERSITY to promote and safegaurd free and open inquiry by faculty, students and others. To further this policy, the UNIVERSITY shall retain the right to publish the TECHNOLOGY and UNIVERSITY IMPROVEMENTS. However, the UNIVERSITY agrees that prior to publishing any TECHNOLOGY and UNIVERSITY IMPROVEMENTS that are not the subject of a U.S. APPLICATION, the UNIVERSITY will provide COMPANY with a copy of the paper at least ninety (90) days prior to publication to allow COMPANY to review the paper and inform the UNIVERSITY whether to file any APPLICATIONS on any of its contents.

ARTICLE IX

INDEMNIFICATION AND INSURANCE

9.1 COMPANY agrees to indemnify the UNIVERSITY and hold the UNIVERSITY harmless against all liabilities, demands, damages, expenses, or losses arising (i) from the manufacture, use lease, sale or other disposition of a PRODUCT by COMPANY or a SUBLICENSEE, (ii) from a third party's use of a PRODUCT purchased, leased, or otherwise acquired from COMPANY or a SUBLICENSEE, or (iii) from a third party's manufacture of a PRODUCT at the request of COMPANY or a SUBLICENSEE.

9.2 COMPANY agrees to maintain and have SUBLICENSEES maintain liability insurance to insure against any of the above liabilities and to name the UNIVERSITY as coinsured. At the UNIVERSITY's request, COMPANY shall provide UNIVERSITY with certification of such insurance.

9.3 The provisions of this article shall survive termination of this agreement.

ARTICLE X

WARRANTIES AND LIMITATIONS

10.1 The UNIVERSITY and COMPANY each represent and warrant that they have the right to enter into this agreement. The UNIVERSITY warrants that it has the right to convey to COMPANY the rights granted under this agreement.

10.2 The UNIVERSITY warrants that it is the sole owner of the TECHNOLOGY, of U.S. Application No. 045,888, and of International Application No. PCT/US88/01342.

10.3 The UNIVERSITY makes no representation or warranty that filed APPLICATIONS will result in issued PATENTS.

10.4 The UNIVERSITY makes not representations or warranties concerning the validity or scope of any PATENTS.

10.5 The UNIVERSITY does not warrant that any PRODUCT made, used, or sold, leased or otherwise disposed of under the license of this agreement is or will be free from infringement of patents of third persons.

10.6 Nothing herein shall be construed to grant COMPANY rights under any applications or patents other than APPLICATIONS and PATENTS.

10.7 The UNIVERSITY does not make any representations, extend any warranties of any kind, express or implied, or assume any responsibility whatever concerning the manufacture, use, or sale, lease or other disposition by COMPANY or its vendees or transferees of PRODUCTS.

ARTICLE XI

UNIVERSITY RESEARCH

11.1 COMPANY agrees to fund additional UNIVERSITY research concerning the TECHNOLOGY providing Dr. Warren Warwick remains employed by the UNIVERSITY and is the principal investigator for such research. This funding shall be for a minimum of $10,000 a year for three (3) years. The parties agree to negotiate the terms of a research agreement in good faith, except that the results of such research shall be subject to the terms and conditions of this present agreement as UNIVERSITY IMPROVEMENTS. The UNIVERSITY shall own any results of the research, and shall hold title to any patent that issues for which a UNIVERSITY employee is named as the sole inventor. In order to preserve rights to any intellectual property that may be developed from the COMPANY-sponsored research, the UNIVERSITY shall submit a copy of any manuscript to the COMPANY at least sixty (60) days before any publication. The UNIVERSITY shall cause a patent

application to be filed at COMPANY request before any publication. The COMPANY shall have an absolute right to delete its own proprietary information from any manuscript.

11.2 The UNIVERSITY, Dr. Warren Warwick and Leland Hansen agree that during the first five (5) years following the effective date of this agreement Dr. Warwick and Leland Hansen shall not seek or obtain funding for the purpose of doing research to develop the TECHNOLOGY and/or IMPROVEMENTS from sources that would put restrictions on licensing the results of such research to COMPANY. However, nothing herein shall be construed to limit Dr. Warren Warwick and/or Leland Hansen from seeking and obtaining Federal Government funding for research concerning the TECHNOLOGY and/or IMPROVEMENTS. COMPANY understands that a UNIVERSITY license to COMPANY for the results of such Government funded research shall be subject to Government regulations (a copy of the current regulations is attached to this agreement), including a royalty-free right for the Government to use any inventions for Government purposes.

ARTICLE XII

MISCELLANEOUS PROVISIONS

12.1 This agreement shall be binding upon and be to the benefit of the parties hereto and their heirs, successors and assignees. However, neither party shall assign this agreement, in whole or in part, without the written consent of the other.

12.2 This agreement shall be governed by the Laws of the State of Minnesota. All disputes arising out of or relating to this agreement (including any questions of fraud or questions concerning the validity or enforceability of this agreement or any of the rights herein conveyed) shall be settled by arbitration to be held in Saint Paul, Minnesota. Such arbitration shall be held in accordance with the then-existing Commercial Rules of the American Arbitration Association. The arbitration shall be speedily concluded with the hearing to take place and the award to be made within ninety (90) days of the filing of any demand for arbitration. Judgment upon the award of all or a majority of the arbitrators shall be binding upon the parties hereto and may be entered in any court having jurisdiction. Specific performance and injunctive relief may be ordered by the award. Costs and attorney fees shall be paid as the Arbitrators' award shall specify. As the sole exception to arbitration, each party shall have the right to obtain injunctive relief, only, from any court having jurisdiction so as to preserve that party's rights for resolution in any pending or imminent arbitration proceedings, but no such injunction shall prohibit or postpone such arbitration proceedings and the injunctions may be modified or vacated as a result of the arbitration award. This paragraph 12.2 shall survive any termination of this Agreement.

12.3 For purposes of mailings of notices (which shall be in writing), payments, or other communications, the addresses of the parties are given below.

In the case of the UNIVERSITY

Regents of the University of Minnesota
Office of Patents and Licensing
Administrative Services Center
1919 University Avenue, 5th Floor
St. Paul, MN 55104

New Address 3/15/91

1100 Washington Ave South
Suite 201
Minneapolis, MN 55415-1221

In the case of COMPANY

American BioSystems, Inc.
Attn: President
750 Walnut Street
Marine on St. Croix, MN 55047

12.4 No term or provision of this agreement shall be waived and not breach excused unless such waiver or consent shall be in writing and signed by the party claimed to have waived or consented. No waiver of a breach shall be deemed to be a waiver of a different or subsequent breach.

12.5 This agreement may not be modified, changed or terminated orally. No change, modification, addition or amendment shall be valid unless in writing and signed by the parties hereto.

12.6 This agreement constitutes and contains the entire agreement of the parties respecting its subject matter and supersedes any and all prior negotiations, correspondence, understandings, and agreements, whether written or oral, between the parties respecting its subject matter.

IN WITNESS of this agreement, the UNIVERSITY and COMPANY have caused this agreement to be executed by their duly authorized officers on the dates indicated.

REGENTS OF THE UNIVERSITY OF MINNESOTA

By _____

Title John F. Thuente Director, Patents & Licensing

Date 11/1/88

AMERICAN BIOSYSTEMS, INC.

By _____

Title President

Date 11/2/88

[redacted]

By their signatures below, Leland Hansen and Dr. Warren Warwick acknowledge that they have read and understood this agreement and have not objections to its terms. Leland Hansen and Dr. Warren Warwick also hereby agree to be personally bound by the obligations specified in 2.2, 8.1, and 11.2.

Warren Warwick

Leland Hansen

CONFIDENTIAL – FOR ATTORNEY'S EYES ONLY

ABI 000209

Law Offices
BARTZ & BARTZ
A Professional Association

Mary A. Bartz
R. John Bartz
Richard O. Bartz

Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435

Tel.: (952) 920-3959
Fax: (952) 920-6494
E-Mail: bartzpa@mcleodusa.net

April 17, 2001

Cyrus A. Morton
Oppenheimer Wolff & Donnelly LLP
Plaza VII, Suite 3310
45 South Seventh Street
Minneapolis, MN 55402

RE: American Biosystems, Inc. v. Electromed, Inc.
Civil Action No. 00-2646 DWF/SRN
Your File: 12653/13 File: E100.18.1

Dear Mr. Morton:

We have your letter of April 11, 2001 and the license agreement with the University of the Regents of Minnesota concerning U.S. Patent application Serial No. 45,888, now U.S. Patent 4,838,263.

We have reviewed patent '263 and ordered its file history.

Patent '263 discloses two embodiments of an oscillatory sheet compression apparatus. The preferred embodiment 101 is shown in Figure 3.

Figure 2

As shown in Figure 2, a rotary valve 22 driven with an electric motor 53 is rotated to sequentially supply vest bladder 16 with air under pressure and vent the air from the vest bladder 16. A first blower 26 operates to supply air to valve 22. A solenoid valve 24 controls the flow of air to valve 22. An operator controlled switch 30 is used to operate the solenoid valve between open and closed positions. A second blower 62 connected with hoses 66 to 68 to rotary valve 22 operates to vent air from the vest bladder 16.

A first manual flow valve 46 located between blower 26 and vest bladder 16 provides adjustment for regulating the flow volume or pulse strength to vest bladder 16. A second manual flow valve 64 located between rotary valve 22 and blower 22 controls the flow of air or venting of air from vest bladder 16. Valves 46 and 64 cooperate with each other to control the pressurized air in the vest bladder 16.

Figure 3

As shown in Figure 3, first and second bellows 88 and 90 are operated with a crankshaft 92 and rods 102 to generate air pressure and pulse air in vest bladder 16. An electric motor 92 drives

crankshaft 96 which expands and contracts bellows 88 and 90. Bellows 90 pumps air into a tank 130. A manually operated solenoid valve 132 controls the flow of air to a hose 114 connected bellows 88 with vest 16. Bellows 88 compresses air in and evacuates air out of vest bladder at a rate of typically between 10 to 30 hertz. A tube 116 having an open end 118 connected to hose 114 is used by the person to vent air from vest bladder 16.

The Electromed Medpulse 2000 respiratory vest system does not have a rotary valve to sequentially apply a vest bladder with air under pressure and vent air from the vest bladder. The apparatus disclosed in Figure 2 of patent '268 is not present in the Electromed Medpulse 2000 system.

The Electromed Medpulse 2000 respiratory vest system does not have a bellows to generate air pressure and another bellows to pulse the air in the vest bladder. There is no tank for storing air under pressure and a manually controlled valve for allowing air to flow from the tank into a hose leading to the vest bladder. A vent tube is not used by a person to vent air from the vest bladder. The apparatus disclosed in Figure 3 of patent '268 is not present in the Electromed Medpulse 2000 system.

Claim 1 of patent '263 has four "means" clauses. These "means" must be construed to cover the corresponding structure, material, or acts described in the specification and equivalent thereof. 35 U.S.C. 112 paragraph 6. The proposed complaint alleges direct or literal infringement of claims of the '263 patent. The doctrine of equivalence does not apply to literal infringement.

It is Electromed's position that there is no basis for alleging that the Electromed Medpulse 2000 respiration vent system literally infringes claims of patent '263. Since there is no basis for infringement of patent '263, there is no basis for filing the amended complaint. The amended complaint will only waste the court's time and increase Electromed's and American Biosystems, Inc.'s cost.

In the event that ABI continues with the amended complaint, Electromed will consider joining the Regents of the University and adding unfair competition, patent invalidity, and other counterclaims.

We suggest the ABI limit this case to patent '662.

Very truly yours,

BARTZ & BARTZ, P.A.

Richard O. Bartz

Richard O. Bartz
Attorney at Law

5

OPPENHEIMER

OPPENHEIMER WOLFF & DONNELLY LLP

Plaza VII, Suite 3300
4[illegible]h Seventh Street
Minneapolis, MN 55402-1609

612.607.7000
Fax 612.607.7100

Direct Dial: *612.607.7354*
E-Mail: *C Morton@oppenheimer.com*

Brussels
Geneva
Los Angeles
Minneapolis
New York
Orange County
Paris
Silicon Valley
Washington, D.C.
oppenheimer.com

April 24, 2001

VIA U.S. MAIL

Richard O. Bartz, Esq.
Bartz & Bartz
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435

Re: American Biosystems, Inc. v. Electromed, Inc.
Court File Number: 00-2646 DWF/SRN
Our File No.: 12653/13

Dear Mr. Bartz:

This letter is an attempt to summarize all of the outstanding discovery issues in the case regarding Electromed's responses to ABI's Interrogatories and Document Requests. ABI's final position on its proposed amended complaint is also included.

Discovery Deficiencies

I will begin with Electromed's Interrogatory Responses with regard to your general and repeated specific objections that the interrogatories request confidential information not relevant to infringement. I have two comments: 1) a protective order is on file with an AEO provisions under which the information may be produced; and 2) the scope of discovery under FRCP 26 is not limited to the issue of infringement and includes all unresolved issues in the case. Thus, Electromed is obligated to provide full discovery related to every issue in the case. Specific interrogatory response objections and requests for clarification are as follows:

INTERROGATORY NO. 2: Electromed must provide the dates of sale, the customer, the number of units sold to that customer and the price as requested by the interrogatory. Note that the interrogatory is not limited to "commercial" sales and thus must be answered for all sales.

INTERROGATORY NO. 5: As mentioned above, this interrogatory is not limited to the issue of infringement and does not request any information that cannot be produced under the protective order. As such, Electromed's answer must be supplemented if the persons provided are not the only person knowledgeable about the categories listed.

INTERROGATORY NO. 6: As mentioned above, this interrogatory is not limited to the issue of infringement and does not request any information that cannot be produced under the protective order. Additionally, this interrogatory is not limited to studies, reports and the like conducted in anticipation of suit. All studies, reports, or analyses relating to the manufacture, marketing or sale of respiratory vest systems must be identified.

INTERROGATORY NO. 7: It would appear that you have identified only the dates of conception and reduction to practice of Electromed's earliest device. These dates, and the sale dates be they commercial, experimental or otherwise must be identified for all models including the MedPulse 2000.

ABI's objections to Electromed's responses to the first set of document requests are as follows:

DOCUMENT REQUEST NO. 3: The production is obviously incomplete. the only documents produced are a few hand sketches and mechanical drawings bates numbered 074-086. Additional documents must exist. In particular, documents related to the electrical components of the device must exist including information regarding vendors, invoices, schematics, specifications and the like. These documents must be produced. Additionally, the handwriting at the top of Bates No. 074 is cut off. A complete copy must be provided.

DOCUMENT REQUEST NO. 4: If Electromed's prototype respiratory vest systems can be made available then they must be because it is certainly easier for Electromed to find them than ABI. Electromed should note its continuing duty to supplement this and every interrogatory.

DOCUMENT REQUEST NO. 5: No document responsive to this request have been produced despite your indication that this would be. Electromed must immediately produce documents, corresponding to Document Request No. 5 in which ABI requested copies of documents referring or relating to testing done by Defendant of any respiratory vest system.

DOCUMENT REQUEST NO. 6: If Electromed had knowledge of the '662 Patent prior to suit, such documentation must be produced. In particular, if any patent search uncovered the '662 Patent, that documentation must be produced.

DOCUMENT REQUEST NO. 7: Electromed's response of "none" defies common sense. Electromed must have documentation regarding its decision to develop its respiratory vest systems. These documents must be produced.

DOCUMENT REQUEST NO. 10: You have indicated that 20 MedPulse 2000 systems have been sold for testing purposes. Documentation regarding this transaction must be produced.

DOCUMENT REQUEST NO. 11: Electromed has identified potential witnesses in response to interrogatories. Documents relating to these persons must be produced.

DOCUMENT REQUEST NO. 12: Again, only mechanical and no electrical documentation has been produced. There are numerous aspects of the MedPulse 2000 about which no documents have been produced. Electromed must supplement its response.

DOCUMENT REQUEST NO. 14: Again, there must be documentation of Electromed's sale of the 20 devices mentioned.

DOCUMENT REQUEST NO. 18: Your response indicates that testing documents do exist. They must be collected and produced.

DOCUMENT REQUEST NO. 22: Electromed must produce the U.S. and Canadian patent applications that were referenced in its response.

DOCUMENT REQUEST NO. 23: The financial statements prior to the '662 issuance must be produced as soon as the '263 Patent to *Warwick* is added to the complaint. Moreover, your simple assertion that the MedPulse 2000 is exempt from infringement under 35 U.S.C. § 271 does not preclude discovery. Complete documentation of this assertion has not been produced and this issue has not been resolved. All responsive documents must be produced.

DOCUMENT REQUEST NO. 24: Again documentation of the sale of at least the 20 devices indicated must be produced.

Bates ranges 1-20 and 87-113 are missing from the produced documents. These pages must be produced or put in a privilege log. Furthermore, it is clear that additional documents beyond the 20 pages produced that are "presently available" must be collected and produced. If this task is too burdensome, might I suggest producing all documents as they are kept in the ordinary course of business. It should also be noted that the lack of production thus far has hindered ABI's ability to complete its claim chart. Full document production must occur before additional scheduling order deadlines are jeopardized.

Please respond in full to these objections to Electromed's responses no later than May 4, 2001.

Amended Complaint

Turning to the question of amending the Complaint to assert U.S. Patent 4,838,263, I received your letter of April 17, 2001 indicating your position that ABI has no basis for alleging that Electromed infringes this patent. From your letter I have to assume you are opposing amendment of the Complaint on the basis of futility of the amendment. I have already explained the timeliness of this amendment in my letter of April 11, 2001. On the question of futility, Wright, Miller & Kane, *Federal Practice and Procedure*, 2nd Ed., Vol. 6, § 1487 notes that if courts have considered the merits of the claim in ruling on a motion to amend it has been either in the context of whether the "complaint as amended could not withstand a motion to dismiss" or whether the "plaintiff has had sufficient opportunity to state a claim but has failed to do so." pp. 643-645. In the present case, the Complaint as amended clearly states a claim for infringement of the '263 Patent by Electromed's MedPulse 2000. Thus, it states a claim upon which relief can be granted. Moreover, a preliminary analysis of Claim 1 of the '263 Patent vis-

a-vis the Electromed MedPulse 2000 reveals a prima fascia case of infringement. Claim 1 has four primary elements. On the first, it is clear that the Electromed device has a "means for applying a force to the chest of said person. . .including a bladder." The MedPulse 2000 has such a bladder. On the second, it is clear that the MedPulse 2000 has a "means for supplying a continuous regular pattern of pulses." The bellows pump of the MedPulse 2000 device provides such a pattern of pulses. On the third element, a "means for venting said pressurized air from said bladder," it is clear the MedPulse 2000 has such a vent. Finally, on the fourth element, it is clear that the controls for the Electromed device can increase and decrease the pressure within the bladder "in correspondence with the expiration and inspiration breathing frequency of said person." Thus, the futility standard is easily met.

In your letter of April 17, 2001, I believe you make two mistakes in forming your position that ABI's assertion that the Electromed MedPulse 2000 device infringes the '263 Patent is futile. First, you list every last detail of the disclosed structure as being required by the claim. It is well known, that the individual components of an overall structure are not claim limitations. *See, Odetics, Inc. v. Storage Tech., Corp.*, 185 F.3d 1259 (Fed. Cir. 1999). Second, structural aspects that are disclosed but that are not necessary for performing the specification function called for in the claim are also not claim limitations. In general, you have recited every aspect of the structure disclosed in the '263 Patent, and then have asserted that the Electromed device does not have aspects that are not required to perform the functions of the claims. At any rate, a complete analysis in this regard requires a legal determination of the meaning of the claims, the disclosed structure, and a factual application of the disclosed structure to the accused device. This is far beyond what is required to withstand a motion to dismiss based on the pleadings and is thus far beyond what is required to win a motion to amend.

Your continued opposition to this amendment, for the reasons explained above, is so baseless that I would like to note for the record that we would be entitled to costs and fees in having to bring such a motion. You are certainly free to bring a motion for summary judgment later at your discretion, but you have no basis to oppose the amendment. Thus, I again ask you to sign the Stipulation to Amend the Complaint and return it to me by next Friday, April 27, 2001 or we will enlist the Court's assistance.

Sincerely,

Cyrus A. Morton

CAM:slo

6

Law Offices
BARTZ & BARTZ
A Professional Association

Mary A. Bartz
R. John Bartz
Richard O. Bartz

Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435

Tel: (952) 920-6939
Fax: (952) 920-6494
E-Mail: bartzpa@mcleodusa.net

April 23, 2001

Cyrus A. Morton, Esq.
Oppenheimer, Wolff & Donnelly, L.L.P.
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402-1609

Re: American Biosystems, Inc. v. Electromed, Inc.
U.S. Patent No. 4,838,263

Dear Mr. Morton:

Enclosed is a copy of U.S. Patent No. 1,898,652 granted February 21, 1933, titled *Direct Air Pulsator*. This patent is not of record in U.S. Patent No. 4,838,263.

Claims 1 and 2 of the '263 patent are anticipated under 35 USC 102 by the disclosure of the '652 patent. These claims are invalid.

Patent '652 discloses:

1. An oscillatory chest compression apparatus for a person.
2. Means for applying a force to the chest. Applicators 45 and 52 are used to apply a force to a person's body including a person's chest.
3. The force applying means includes a bladder shown as a diaphragm 56 mounted on a rigid member 52.
4. The piston 17 connnected with rod 24, disc 20 and drive shaft 19 to motor 11 pulses the air in chamber 14 and supplies a continuous regular pattern of pulses of pressurized air to the bladder at a frequency irrespective of and greater than the breathing frequency of the person. The speed of motor 11 controlled with rheostat 12 controls the reciprocating movement of piston 17 and the air pulse frequency in chamber 14 and applicator which can be greater than the frequency of the person.
5. The valve 50, shown in Figure 6, is used to vent air from the applicator 45.
6. The air pressure relief valve, shown in Figure 5, is adjustable for controlling the pressure of the air in chamber 14 and applicator 52. Valves 31 and 32 can also be adjusted to control the flow of air into and out of chamber 14. A person can adjust these valves to increase and decrease the air pressure in the applicator 52 to correspond with the expiration and inspiration breathing frequency of the person. The air pressure pulses have greater impact with increased air pressure in the applicator and lessor impact with decreased air pressure in the applicator.

Claim 1 fails to comply with 35 USC 112. The claim does not define any structure for "pressurizing air." There is no antecedent basis for the terms "said pressurized air" in lines 7, 10 and 12. A structure of pressurizing air is required for applying a force to the chest, for supplying a continuous regular pattern of pulses, for venting pressurized air, and controlling pressurized air in the bladder. The claim does not define an operable oscillatory chest compression apparatus. This claim is not valid under the provisions of 35 USC 112.

We suggest that the lawsuit be confined to ABI's '662 patent. A civil action on invalid claims opens the litigation to an exceptional case under 35 USC 285 and other defenses.

Very truly yours,

BARTZ & BARTZ, P.A.

Richard O. Bartz

Richard O. Bartz

ROB/gn

Encl.

Feb. 21, 1933. G. A. WILLIAMS 1,898,652

DIRECT AIR PULSATOR

Filed July 8, 1930

Fig. 1.

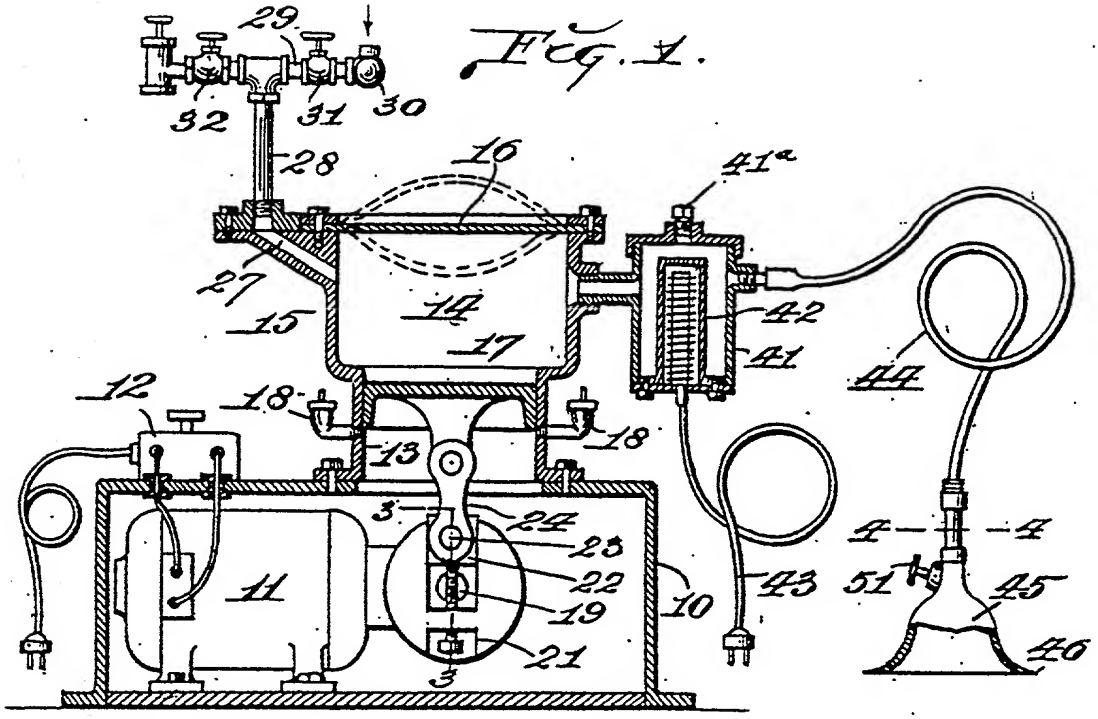


Fig. 2

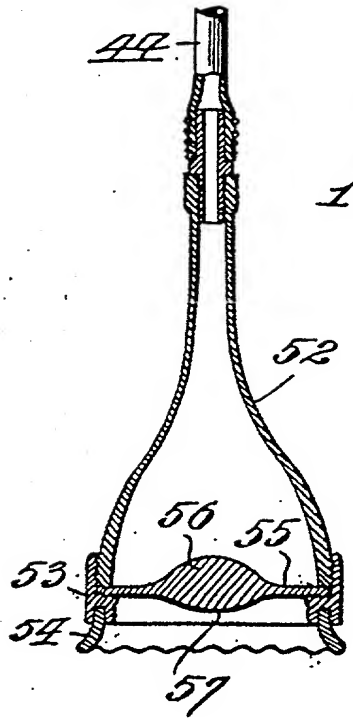


Fig. 3.

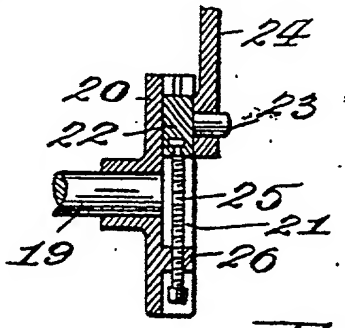


Fig. 4.

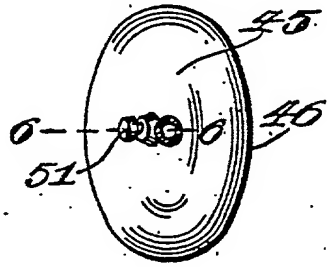


Fig. 5

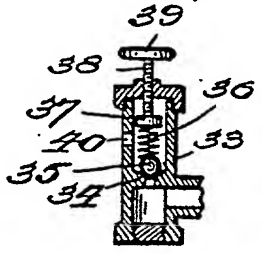
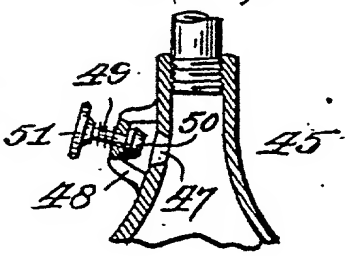


Fig. 6.



INVENTOR,
GEORGE A. WILLIAMS.
BY Martin P. Smith ATTY.

Patented Feb. 21, 1933 1,898,652

UNITED STATES PATENT OFFICE

GEORGE A. WILLIAMS, OF LOS ANGELES, CALIFORNIA

DIRECT AIR PULSATOR

Application filed July 8, 1930. Serial No. 466,373.

My invention relates to an air pulsator and has for its principal object the provision of a relatively simple, practical and inexpensive device wherein the alternate compression and suction of air is utilized for producing pulsations which, through the medium of suitable applicators, may be utilized as a therapeutic medium for the treatment of various bodily ailments and particularly for the gentle massage or treatment of the skin for the purpose of stimulating blood circulation and the treatment of tissues and muscles beneath the skin.

A further object of my invention is, to provide a device of the character referred to wherein a body of air is confined within a chamber, one of the walls of which is elastic and to rapidly compress the confined body of air to produce comparatively rapid alternate pressure and suction through an applicator havng a relatively thin edge that is positioned directly upon the skin so as to produce rapid vibratory suction upon the area covered by the applicator and which action is in the nature of vibratory massage that is highly beneficial in the treatment of various ailments of the body.

Further objects of my invention are to provide simple and efficient means for regulating the action of the air pulsating mechanism; further, to provide means whereby the column of air that passes through the device may be heated or whereby liquid or compounds may be heated and vaporized to produce medicated vapor, further, to provide a pulsator of the character referred to that is comparatively light in weight, strong and durable and very compact so that it will occupy relatively little space when packed for storage or transportation and further, to provide an applicator having a weighted flexible or elastic diaphragm which, when vibrated, will produce relatively light tapping impulses that may be applied with beneficial results to different parts of the body.

With the foregoing and other objects in view, my invention consists in certain novel features of construction and arrangement of parts that will hereinafter be more fully described and claimed and illustrated in the accompanying drawing, in which:

Fig. 1 is a vertical section taken through the center of an air pulsator constructed in accordance with my invention.

Fig. 2 is a vertical section taken through the center of one of the applicators utilized in connection with the pulsator.

Fig. 3 is an enlarged vertical section taken on the line 3—3 of Fig. 1.

Fig. 4 is a horizontal section taken on the line 4—4 of Fig. 1.

Fig. 5 is a vertical section taken through the center of a regulating check valve utilized for controlling the outlet of air from the compression chamber of the pulsator.

Fig. 6 is an enlarged detail section taken approximately on the line 6—6 of Fig. 4.

Referring by numerals to the accompanying drawing which illustrates a practical embodiment of my invention, 10 designates a box-like container, which forms the base of the pulsator and arranged therein is a small electric motor 11 that is controlled by a rheostat 12, the latter being preferably located on the exterior of the housing 10.

Secured to and projecting upwardly from the top of housing 10 is a short cylinder 13 and the upper end thereof communicates with a combined compression and suction chamber 14 that is formed within a housing 15.

The upper end of chamber 14 is closed by a head 16 of elastic material, preferably rubber or composition having rubber as its principal ingredient and the edges of which head is secured to the upper end of housing 15.

Arranged for reciprocatory movement within cylinder 13 is a piston 17 and seated in the wall of cylinder 13 are grease cups 18, by means of which the piston is lubricated.

The shaft of motor 11 is connected by suitable gearing to a short horizontally disposed shaft 19 that is journalled in suitable bearings and the outer end of the shaft carries a disc 20 in the outer face of which is formed a diametrically arranged slot 21.

Arranged for sliding movement in this

slot is a block 22 from which projects a wrist pin 23 and connecting this wrist pin and the piston 7 is a link or connecting rod 24. Block 22 that carries the wrist pin is adjustable toward and away from the center of the disc by the screw 25 that is arranged for rotation in a lug 26 on said disc.

Formed through the side wall of housing 15 and communicating with chamber 14 is a duct 27 and communicating with the upper end of said duct is a short vertically disposed tube 28 that is connected at its upper end to a short horizontally disposed tube 29. Located on one end of said tube 29 is an inwardly opening check valve 30 and located between said check valve and the center of tube 29 that is connected to tube 28 is an ordinary shutoff valve 31.

Located in the opposite side portion of tube 29 is an ordinary shutoff valve 32 and connected thereto is a valve housing 33 provided with a seat 34 on which normally rests a check valve 35. Bearing on top of check valve 35 is a relatively light expansive spring 36 and the upper end of said spring bears against a disc 37 that is carried by a screw rod 38 and the latter being threaded through the top of the valve housing 33 and carrying on its upper end a hand wheel 39.

Formed through the wall of valve housing 33 above check valve 35 is an outlet port 40.

Detachably secured to the side of housing 15 is a housing 41 within which is arranged an electric heating element 42, to which is connected a cord and plug 43 so that said heating element may be readily connected to a suitable source of current supply, for instance, the household lighting system.

Connected to housing 41 is one end of a flexible tube 44 which may be of any desired length and to which are detachably connected the applicators forming a part of my improved pulsator.

In Figs. 1 and 4 I have shown a form of applicator which comprises a substantially bell-shaped member 45 of rubber or analogous material, the lower end of which terminates in an outwardly presented flange 46 that gradually decreases in thickness towards its outer edge.

Formed in the upper portion of the body of the applicator 45 is a port 47 and arranged for sliding movement through a bracket 48 on the applicator directly over this port, is a spring held rod 49 carrying at its inner end a valve 50 that is adapted to close port 47. The outer end of rod 49 carries a disc 51.

The form of applicator just described is designed particularly for imparting pulsating suction to the surface to which the flanged edge of the applicator is applied.

In the form of applicator illustrated in Fig. 2, the upper end of an elongated bell-shaped member 52 is detachably connected to the end of flexible tube 44 and removably seated on the large end of this body is a ring 53 that carries a contact ring 54 of soft flexible material such as rubber.

A diaphragm 55 of rubber or analogous material has its edge clamped between ring 53 and the end of the applicator body 52 and formed integral with or fixed to the central portion of the diaphragm 55 is a weight 56 having a centrally arranged convex outer face 57.

The lower edge of the contact ring 54 is preferably notched or serrated so as to permit air to readily pass into and out of the chamber surrounded by said ring while the latter is positioned on the surface to be treated and the diaphragm 55 is being vibrated.

In the operation of my improved pulsator, motor 11, when connected to a suitable source of current supply, drives shaft 19 carrying disc 20 and through connecting link 24, piston 17 will be reciprocated in its cylinder, thereby intermittently compressing and imparting suction to the body of air within chamber 14.

The elastic diaphragm of head 16 will yieldingly resist the compression of the air in chamber 14 and during operation the elastic head will be rapidly vibrated to the positions illustrated by dotted lines in Fig. 1.

Chamber 14 within housing 15 and the heating chamber within housing 41 combine to form an air chamber of considerable volume much greater than the air chamber through flexible tube 44 and the chamber within applicator 45 and said relatively large air chamber having a yielding wall 16. Such construction enables a comparatively large volume of air to be maintained in transit through the apparatus and the flow of such large volume of air is relatively slow.

Thus the piston in operation effects a pulsation of this relatively large volume of air and comparatively little air is forced out of the edge 46 of the applicator that is in contact with the surface that is being treated. This pulsating effect is greatly enhanced by the provision of the flexible wall 16 for if such flexible wall were not used, the operation of the piston 17 would produce a direct rapid flow of air through the apparatus and the applicator rather than the yielding gentle pressure of pulsations produced by the alternate compression and suction of air.

Further, by providing means for pulsating a relatively large volume of air, the flow of said air through the apparatus is comparatively slow and as a result the heating element within the housing 41 is able to more uniformly heat the air to the de-

sired or proper degree and which effect could not be produced if the air were forced rapidly through the heating chamber.

On the suction stroke of the piston 17 air enters through inlet check valve 30 and passes from thence through connections 29 and 28 and duct 27 into chamber 14 and on the compression stroke of the piston a certain amount of air will pass out through duct 27 and connections 28 and 29 and thence past spring held check valve 35 and thence through outlet port 40.

The tension of spring 36 that resists the opening movement of check valve 35 may be regulated by manipulation of the screw rod 38.

The comparatively rapid pulsation of the body of air within the chamber 14 having the elastic head 16 will impart corresponding movement to the column of air within the heating chamber 41, flexible tube 44 and applicator 45 and when the thin edge 46 of this applicator is positioned on the body that area that is covered by the applicator will be subject to the rapid pulsations of the column of air, thereby imparting to the area under treatment relatively rapid pressure and suction or vibratory or pulsating massage that is highly beneficial in increasing circulation of the blood through the skin and underlying tissues and muscles.

During the compression strokes of the pulsator a relatively small quantity of air may be forced out beneath the thin edge of the applicator and during the suction strokes the thin edge of said applicator will be drawn against the skin, thereby producing a mild degree of suction upon the area covered by the applicator. This pulsating massage or vibratory action may be accurately controlled by placing a finger of the hand that holds the applicator upon disc 51 and pressing valve 50 inwardly to control the opening 47. This opening 47 is normally open to permit a free flow of air through said opening, but when said opening is closed or partially closed, the greater portion of the air movement through the applicator will take place between the thin edge 46 thereof and the surface to which said edge is applied so that the desired pulsating massage effect is produced.

Where the form of applicator illustrated in Fig. 2 is ultilized, the pulsating body and column of air imparts relatively rapid movement to the flexible or elastic diaphragm 55 and the movement of the latter imparts relatively light tapping blows to the surface that is covered by the flexible ring 54 carried by the applicator and the notched or serrated edge of said ring permits air to circulate freely through the chamber surrounded by ring 54 and beneath the elastic weighted diaphragm 55.

The length of the stroke of piston 17 may be accurately regulated by adjustment of block 22 in slot 21 and which adjustment is brought about by manipulation of screw 25 that is connected to said block 22. This adjustment of the block carrying the wrist pin permits the piston throw to be graduated to any desired degree and consequently enables the volume or strength of the pulsations to be varied throughout a comparatively wide range. Where the wrist pin is adjusted so that its axis is to a slight degree eccentric relative to the axis of shaft 19, the pulsations are so faint as to be hardly perceptible when the applicator is placed on the skin, although the suction is readily noticeable.

I have shown the applicator 45 as being oval when viewed in plan and while I prefer to make the applicator of this shape it will be understood that said applicator may be round or polygonal.

By connecting the plug of cord 43 to a suitable source of electric current supply the heating element 42 will be heated so as to heat the column of air that passes through container 41 and the flexible tube 44 that carries the applicator.

If desired medicinal compounds, either liquid or in semi-liquid form may be delivered into the container 41 and the column of air passing therethrough and the heat produced within the container will vaporize the liquid or semi-liquid, thereby producing medicated vapor that is highly beneficial in the treatment of various ailments.

The top of the container 41 is provided with an opening that is normally closed by a screw plug 41ª and such construction permits liquids or semi-liquids to be delivered into the container.

If desired the air heater and evaporating chamber 41 may be dispensed with and the flexible tube 44 that carries the applicator may be directly connected to housing 15.

Thus it will be seen that I have provided an air pulsator that is relatively simple in construction and which may be conveniently and economically employed for producing relatively rapid and rythmic air pulsations for the treatment of various bodily ailments and particularly for the gentle massage of skin, for the stimulation of blood circulation therein and the beneficial treatment of tissues and muscles beneath the skin.

It will be understood that minor changes in the size, form and construction of the various parts of my improved direct air pulsator may be made and substituted for those herein shown and described without departing from the spirit of my invention, the scope of which is set forth in the appended claims.

I claim as my invention:

1. In an air pulsator, the combination with a duct and means for producing pulsa-

tions of the air column that passes through said duct, of an applicator carried by said duct, an elastic weighted diaphragm carried by said applicator and an elastic contact ring carried by said applicator and surrounding and arranged in front of said weighted diaphram.

2. In an air pulsator, the combination with a duct and means for producing pulsations of the air column that passes through said duct, of an applicator carried by said duct, a contact ring carried by said applicator, a weighted elastic diaphragm arranged within said applicator adjacent to said contact ring and a flexible contact ring carried by the end of said applicator and surrounding and arranged in front of said weighted diaphragm.

3. In an air pulsator, the combination with a supporting structure, a motor arranged within said structure, a cylinder on top of said structure, said cylinder having an air inlet and an air outlet, an elastic member closing the head of said cylinder so as to produce variable yielding pressure on the entire body of air within said cylinder as said air is pulsated, a piston arranged for reciprocatory movement within said cylinder, a housing connected to said air outlet of said cylinder and a flexible tube leading from said housing and adapted for connection to an applicator.

4. In an air pulsator, the combination with a supporting structure, a motor arranged within said structure, a cylinder on top of said structure, said cylinder having an air inlet and an air outlet, an elastic member closing the head of said cylinder so as to produce variable yielding pressure on the entire body of air within said cylinder as said air is pulsated, a piston arranged for reciprocatory movement within said cylinder, a housing connected to said air outlet of said cylinder, a flexible tube leading from said housing and adapted for connection to an applicator and means for heating the entire volume of pulsated air as it passes through said cylinder and housing.

In testimony whereof I affix my signature.

GEORGE A. WILLIAMS.

OPPENHEIMER

OPPENHEIMER WOLFF & DONNELLY LLP

VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402-1609

612.607.7000
Fax 612.607.7100

Direct Dial: 612.607.7384
E-Mail: DMcKinley@oppenheimer.com

April 27, 2001

Richard O. Bartz, Esq.
Bartz & Bartz
Southdale Office Centre
6750 France Avenue S., Ste. 350
Edina, Minnesota 55435

Re: American Biosystems, Inc. v. Electromed, Inc.
Court No.: 00-2646DWF/SRN
Our File No. 12653/13

Dear Mr. Bartz:

In response to your letter of April 23, 2001, in which you assert that claims 1 and 2 of U.S. Patent 4,838,263 are anticipated under 35 U.S.C. 102 by the disclosure of U.S. Patent No. 1,898,652, we have reviewed the disclosure of the '652 patent. Your accusations are incorrect.

One needs look no further than the first element of claim 1 of the '263 patent to realize that the '652 patent has no impact on the validity of the '263 patent. The first element is "means for applying a force to the chest of said person, said force applying means including a bladder for receiving pressurized air;". The '652 patent neither teaches nor discloses such a bladder. The most liberal definition of a bladder would not include a diaphragm mounted on a rigid member.

One skilled in the art would conclude that the reason the '652 patent teaches using a diaphragm mounted on a rigid member is to accomplish "comparatively rapid alternate pressure and suction through an applicator ...", an object of the invention. One cannot draw a vacuum on a bladder.

Similarly obvious reasons why none of the other elements of the claims of the '263 patent are anticipated by the '652 patent are readily apparent. A civil action on invalid claims would clearly not pass muster.

Very sincerely,

David J. McKinley
DJM:jb

8

Law Offices
BARTZ & BARTZ
A Professional Association

Mary A. Bartz
R. John Bartz
Richard O. Bartz

Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435

Tel.: (952) 920-3959
Fax: (952) 920-6494
E-Mail: bartzpa@mcleodusa.net

April 30, 2001

Cyrus A. Morton, Esq.
Oppenheimer, Wolff & Donnelly, L.L.P.
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402-1609

Re: American Biosystems, Inc. v. Electromed, Inc.
Civil Action No.: 00-2646 DWF/SRN

Dear Mr. Morton:

We have received the file history of U.S. Patent No. 4,838,263.

Claim 1 was twice rejected as unpatentable over the prior art patents to *Polzin et al* (2,780,222) and *Akerman et al* (2,588,192). Claim 1 was twice amended in view of the rejection of the claim on the prior art. Enclosed are copies of the amendments of February 1, 1988 and November 3, 1988 that include the amendments to Claim 1. Amended Claim 1 of the patent application Claim 1 of the '263 patent.

The amendments to Claim 1 preclude the application of the doctrine of equivalence to this claim. The amendments to Claim 1 and the remarks create prosecution history estoppel. There is no range of equivalents available for amended Claim 1. *See; Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558 (Fed. Cir. 2000) and *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 238 F.3d 1341 (Fed. Cir. 2001).

The Electromed 2000 Respiratory Vest System does not infringe Claim 1 of the '263 patent under the doctrine of equivalence. There is no basis for a claim of infringement of Claim 1 of the '263 patent by Electromed's making, using and selling the MedPulse 2000 Respiratory Vest System.

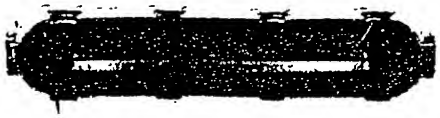
We note that the file history of the '263 patent does not show that U.S. Patent No. 1,898,652 is of record.

Very truly yours,

BARTZ & BARTZ, P.A.

Richard O. Bartz

Richard O. Bartz
ROB/gn
Encl.



4838263

045888	PATENT DATE JUN 13 1989	PATENT NUMBER 4838263

SERIAL NUMBER	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT	EXAMINER
07/045,888	05/01/87	128	30.2	332	Flaxman

APPLICANTS

WARREN J. WARWICK, MINNEAPOLIS, MN; LELAND G. HANSEN, ST. PAUL, MN.

CONTINUING DATA********
VERIFIED
HF 9/11/87

FOREIGN/PCT APPLICATIONS********
VERIFIED
HF 9/11/87

FOREIGN FILING LICENSE GRANTED 06/10/87 ***** SMALL ENTITY *****

foreign priority claimed	35 USC 119 conditions met	Verified and Acknowledged	Examiner's Initials	AS FILED	STATE OR COUNTRY	SHEETS DRWGS.	TOTAL CLAIMS	INDEP. CLAIMS	FILING FEE RECEIVED	ATTORNEY'S DOCKET NO.
☐ yes ☑ no	☐ yes ☐ no		HF		MN	2	12	3	$ 170.00	M8G600.85-US

Curtis B. Hamre
MERCHANT, GOULD, SMITH, EDELL,
WELTER & SCHMIDT, P.A.
3100 Norwest Center
90 South Seventh Street
Minneapolis, Minnesota 55402

TITLE
CHEST COMPRESSION APPARATUS

U.S. DEPT. of COMM.-Pat. & TM Office— PTO-436L (rev. 10-78)

SN

PARTS OF APPLICATION FILED SEPARATELY

NOTICE OF ALLOWANCE MAILED	PREPARED FOR ISSUE	CLAIMS ALLOWED
11-22-88	Howard Flaxman, Assistant Examiner; Rita Kent, Docket Clerk	Total Claims 8; Print Claim 1

11-21

ISSUE FEE		DRAWING		
Amount Due	Date Paid	Sheets Drwg.	Figs. Drwg.	Print Fig.
280.00	2/16/89	2	4	1+4

RICHARD J. APLEY
S. P. E.
ART UNIT 332
Primary Examiner

ISSUE CLASSIFICATION		ISSUE BATCH NUMBER
Class	Subclass	
128	30.2	008

Label Area

S/N 045,888

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Warren Warwick et al. Examiner: Flaxman, H.

Serial # : 045,888 Group Art Unit: 332

Filed : May 1, 1987 Docket: M&G 600.85-US-01

Title : CHEST COMPRESSION APPARATUS

a Gemellion 2-25-88

AMENDMENT UNDER RULE 111

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Dear Sir:

In response to the Official Action dated September 28, 1987, please amend this application as follows:

In the Specification

Page 5, line 33, replace "door" with --blower--.

Page 8, line 17, delete "not" (first instance).

Page 11, line 1, replace "92" with --93--.

Page 11, line 2, replace "92" with --93--.

In the Claims

Kindly rewrite claims 1 and 7 as follows:

1. (Amended) Oscillatory chest compression apparatus for a person, comprising:

means for applying a force to the chest of said person, said force applying means including a bladder for receiving pressurized air;

means for supplying a continuous regular pattern of pulses of said pressurized air to said bladder, said pulse supplying means including means for maintaining a pulse frequency greater than the breathing frequency of said person;

means for venting said pressurized air from said bladder; and

manual means for alternately controlling said pulse supplying means and said venting means so that air pressure in said bladder can be increased and decreased in correspondence with the breathing frequency of said person.

7. (Amended) Apparatus in accordance with claim 1 wherein said pulse supplying means includes:

a pressurizing blower providing a first volume rate of air;

a rotary valve and means for driving said valve;

first means for communicating the air between said pressurizing blower and said rotary valve; and

second means for communicating the air between said rotary valve and said bladder[.];

and wherein said venting means includes:

a depressurizing blower evacuating a second volume rate of air, said second volume rate being less than said first volume rate; and

third means for communicating air from said rotary valve to said depressurizing blower.

Please cancel claim 8.

Kindly rewrite claims 9-12 as follows:

9. (Amended) Apparatus in accordance with claim 7 wherein said controlling means includes a stop valve installed in said first communicating means, said controlling means further including means operable by said person [for functioning said stop valve.].

10. (Amended) Oscillatory chest compression apparatus for a person, comprising:

means for applying a force to the chest of said person, said force applying means including a bladder for receiving pressurized air;

means for alternately blowing air into and out of said bladder, said blowing means having pressurizing and depressurizing lines, said blowing means further including a rotary valve alternately open and closed with respect to each of said pressurizing and depressurizing lines, said blowing means including a first fan in said pressurizing line, said first fan having a first volume rate, said blowing means including a second fan in said depressurizing line, said second fan having a second volume rate, said first volume rate being greater than said second volume rate; and

means for switching the pressurizing line of said blowing means on and off.

11. (Amended) A method to aid a person in clearing mucus from his/her lungs, comprising the steps of:

restraining a bladder adjacent said person's chest;

[alternately cycling] manually controlling increasing and decreasing pressure at the breathing frequency of said person of a continuous regular pattern of pressurized air pulses into said bladder, said air pulses having a frequency greater than the breathing frequency of said person [at a relatively constant rate and evacuating said bladder, said cycling being in rhythm with said person's breathing, said bladder evacuation allowing inspiration by said person,] said pressurized air pulsing in said bladder mechanically pounding said person's chest to free mucus in said person's lungs.

12. (Amended) The method in accordance with claim 11 wherein said controlling step includes said person operating a switch to control administration of said pressurized [aid] air pulses to said bladder [and said evacuation of said bladder].

Remarks

Minor corrections have been made to the specification. Claims 1, 7, and 9-12 have been amended. Claim 8 has been cancelled. Claims 1-7 and 9-12 remain in the application, although claims 3-6 have been withdrawn as a result of a provisional election. Re-examination and reconsideration of the application, as amended, are requested.

The Examiner rejected claim 12 under 35 U.S.C. §112, second paragraph, as being indefinite. The correction suggested by the Examiner has been made.

A species election between embodiment 1 shown in Figure 2 and embodiment 2 shown in Figure 3 has been required. Applicant elects the invention of embodiment 1 of Figure 2, claims 1-2 and 7-12. The election is made without traverse.

The Examiner rejected claims 1-2 and 11-12 under 35 U.S.C. §103 as being obvious on consideration of Polzin in view of Ackerman.

Polzin discloses an apparatus for inducing artificial respiration. The apparatus was intended for victims of Polio. The apparatus includes a source of air pressure which is controlled by an electronic timer. The air source provides pressurized air through a sequence valve to a shell fitted on the patient. A second line for evacuating the pressurized air extends from the shell on the patient through the sequence valve back to the air pressure source. A flow control valve 26 is located in the evacuation line. Pressure bleeder valves 28 and 30 are located in each of the pressurization and evacuation

lines. As a back-up to the electrical system, a manual air pump is also provided.

Ackerman also shows an artificial respiration apparatus for Polio victims. The apparatus includes a pump for providing pressurized air to a vest. The air line leading to the vest includes a "Y" thereby providing for a vent line. Solenoid valves are located in each of the pressurization and vent lines. The valves are controlled by an electronic control unit.

Claim 1 is directed to an oscillatory chest compression apparatus which includes means for applying a force including a bladder. The apparatus also includes means for supplying a continuous regular pattern of pulses of pressurized air to the bladder, as well as means for venting the pressurized air from the bladder. The pulse supplying means has means for maintaining a pulse frequency greater than the breathing frequency of the person. The apparatus further includes manual means for alternately controlling the pulse supplying means and the venting means so that air pressure in the bladder can be increased and decreased in correspondence with the breathing frequency of the person.

Polzin provides a single mechanism for cycling or giving a frequency to the air pressure applied to the shell fitted on the patient. Ackerman is similar. The apparatus of claim 1, on the other hand, includes means for supplying a continuous regular pattern of pulses which also includes means for maintaining pulse frequency at a level greater than the breathing frequency of the person. In addition, the apparatus of claim 1 includes manual means for alternately controlling the pulse supplying means and the venting means so that air pressure in the bladder can be increased and decreased in correspondence to the breathing frequency of the person. In this way, pressure to the bladder increases and decreases with the breathing frequency of the person. The pulses of the supplying means have a frequency greater than the breathing frequency and are continuous, but are really only felt by the person when there is pressure in the bladder. The apparatus of claim 1 has pulses of a high frequency superimposed on the pressure build up and release occurring as a result of the manual controlling means operated by the person at his slower breathing rate. The cited art does not disclose or point to the type of apparatus which could have pulses of a high frequency superimposed on pressure build up and release at a low

frequency. The cited art simply discloses machines which can provide a regular pressure build up and release at the low frequency. Claim 1 does not follow from Polzin and Ackerman and is non-obvious thereover.

Claim 2 further defines a particular force applying means.

Claim 11 defines a method comprising the steps of restraining a bladder and then manually controlling increasing and decreasing pressure at the breathing frequency, which pressure is air in the form of a continuous regular pattern of pulses which pulse at a frequency greater than the breathing frequency.

The respirator of Polzin is completely automatic, except in the case of electrical failure when there is a manual pump available for providing low frequency artificial respiration. Ackerman is similar. Neither reference points to manual control of increasing and decreasing the delivery of high frequency pulses at a low frequency breathing rate. Such control, of course, resulting in a build up of pressure and then a release of it. Claim 12 further defines the controlling step to include the person operating a switch which controls the administration of the pressurized air pulses to the bladder. The references have automatic controls.

The Examiner rejected claims 7-10 under 35 U.S.C. §103 as being obvious on consideration of Polzin and Ackerman in view of Borgeas. The Examiner indicates that Borgeas discloses a cycling valve which could be used to replace the sequence valve of Polzin.

Claim 7 further defines the pulse supplying means of claim 1 and includes a pressurizing blower which provides a first volume rate of air and a depressurizing blower which evacuates a second volume rate of air such that the second volume rate is less than the first volume rate.

Since the pressurizing blower and rotary valve provide pulses at a frequency higher than the breathing frequency, the depressurizing must be done in a different way, otherwise there would simply be air in and air out just like Polzin and Ackerman. Rather, with different pressurizing and depressurizing blowers and a manual control on the pressurizing blower, the desired pressure build up and release with superimposed high frequency pulses is obtained. The details of the pulse supplying means of claim 7 are not disclosed or pointed to by the cited art.

Claim 9 further defines the controlling means to be a type which allows use to obtain the pressure build up and release.

In view of the above, it is submitted that the pending claims are in condition for allowance. Reconsideration of the rejections and objections is requested. Allowance of claims 1-7 and 9-12 at an early date is solicited.

Respectfully submitted,

Warren J. Warwick et al.

By their Attorneys,

Merchant, Gould, Smith, Edell,
Welter & Schmidt, P.A.
1600 Midwest Plaza Building
Minneapolis, Minnesota 55402
(612) 332-5300

By Curtis B. Hamre
Curtis B. Hamre
Reg. No. 29,165

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, DC 20231
on 12/3/88 (Date of Deposit)
Curtis B. Hamre
Reg. No 29,165

S/N 045,888

PATENT

RECEIVED
NOV -3 88
GROUP 330

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Warren Warwick et al. Examiner: Flaxman, H.

Serial # : 045,888 Group Art Unit: 332

Filed : May 1, 1987 Docket: M&G 600.85-US-01

Title : CHEST COMPRESSION APPARATUS

AMENDMENT UNDER RULE 116

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Dear Sir:

In response to the Official Action dated May 16, 1988, please amend this application as follows:

In the Claims

Kindly rewrite claim 1 as follows:

1. (Twice Amended) Oscillatory chest compression apparatus for a person, comprising:

means for applying a force to the chest of said person, said force applying means including a bladder for receiving pressurized air;

means for supplying a continuous regular pattern of pulses of said pressurized air to said bladder[, said pulse supplying means including means for maintaining a pulse] at a frequency irrespective of and greater than the breathing frequency of said person;

means for venting said pressurized air from said bladder; and

[manual] means for [alternately] controlling [said pulse supplying means and said venting means so that air pressure] said pressurized air in said bladder so that the pressure therein can be increased and decreased in correspondence with the expiration and inspiration breathing frequency of said person[.] wherein said force is applied by said applying means at the pulse

frequency of said supplying means with greater impact when said controlling means allows increased air pressure in said bladder and with lessor impact when said controlling means allows decreased air pressure in said bladder.

In claim 5, line 1, replace "4" with --1-- and in lines 2-3, delete "in said first communication means".

In claim 9, line 1, replace "8" with --1--.

Kindly rewrite claims 10-12 as follows:

10. (Twice Amended) Oscillatory chest compression apparatus for a person, comprising:

means for applying a force to the chest of said person, said force applying means including a bladder for receiving pressurized air;

means for [alternately] intermittently blowing air into [and out of] said bladder, said blowing means [having pressurizing and depressurizing lines, said blowing means further] including a [rotary] valve [alternately] regularly between open and closed [with respect to each of said pressurizing and depressurizing lines, said blowing means including a first fan in said pressurizing line, said first fan having a first volume rate, said blowing means including a second fan in said depressurizing line, said second fan having a second volume rate, said first volume rate being greater than said second volume rate; and] at a pulse creating frequency irrespective of and greater than the inspiration and expiration breathing pattern of said person, said blowing means also including a fan and means for fluidly communicating from said fan

through said valve to said bladder;

manual means for switching passage of air through said communicating means [the pressurizing line of said blowing means] on and off at a rate corresponding with the inspiration and expiration breathing pattern of said person.

11. (Twice Amended) A method to aid a person [in clearing mucus from his/her lungs] achieve better respiration, comprising the steps of:

restraining a bladder adjacent said person's chest;

[manually controlling increasing and decreasing pressure at the breathing frequency of said person of a continuous regular pattern of pressurized air pulses into said bladder, said air pulses having a frequency greater than the breathing frequency of said person said pressurized air pulsing in said bladder mechanically pounding said person's chest to free mucus in said person's lungs] initiating means for supplying pressurized air pulses from a source to said bladder at a pulse frequency greater than the inspiration and expiration breathing pattern of said person;

closing fluid communication means from said source to said bladder during expiration; and

opening said fluid communication means during inspiration.

12. (Twice Amended) The method in accordance with claim [11] 16, wherein said [controlling step includes] closing and opening steps include said person operating a switch to control administration of said pressurized air pulses to said bladder.

Please add claim 13.

13. The method in accordance with claim 11 including tuning said pulse frequency to said person.

Remarks

Claims 1 and 9-12 have been amended. Claim 13 has been added. Claims 1-7 and 9-13 remain in the application, although claims 3-6 have been withdrawn. Reexamination and reconsideration of the application, as amended, are requested.

The Examiner rejected claim 9 under 35 U.S.C. §112, second paragraph, as being indefinite since it was dependent upon cancelled claim 8. The dependency of claim 9 has been corrected.

The Examiner rejected claims 1-2 and 11-12 under 35 U.S.C. §103 as being obvious on consideration of Polzin in view of Ackerman.

Polzin shows a respirator having a source of air pressure in fluid communication through a positive bypass valve 28 and a sequence valve 32 to a patient shell 12. Polzin further shows fluid communication from the patient shell 12 through sequence valve 32 and negative bypass valve 30 back to the air pressure source or to atmosphere. The sequence valve is controlled by an electronic timer.

Ackerman shows a vest 6.

Claim 1 has been amended to more clearly specify pulse supplying means which provides a continuous pattern of pressurized air pulses to the bladder at a frequency irrespective of and greater than the breathing frequency of the person, in conjunction with means for controlling the pressurized air in the bladder. In this way, the force applied by the bladder to the person at the pulse frequency of the supplying means is applied

with greater impact when the controlling means allows increased air pressure in the bladder and with lesser impact when the controlling means allows decreased air pressure in the bladder.

Polzin only discloses apparatus which aids a person with respiration at the person's breathing rate. The whole purpose of timer 34 is to control sequence valve 32 at the breathing rate of the person. Positive and negative bypass valves 28 and 30 simply adjust the amount of air which flows to and from the patient shell. The valves are shown in detail in Figure 7 to include a rotatable sleeve which varies the size of the opening leading to the sequence valve or leading to atmosphere, depending on the rotational setting of the valve. The valve settings do not change during a single inspiration and expiration of the patient. Such idea is wholly outside of the concept of Polzin since the purpose of the timer is to set the sequence valve at the breathing rate of the person. Contrarily, the supplying means of claim 1 is specifically defined to provide a pulse rate irrespective of and greater than the breathing frequency of the person. Furthermore, a second element of claim 1 in the form of controlling means is provided to specifically allow for an increase and decrease of pressurized air to the bladder in correspondence with expiration and inspiration such that the pulses from the pulse supplying means are superimposed on such increased and decreased pressure. As a consequence, claim 1 does not follow from the cited art and is patentable thereover.

Claim 2 further defines the force supplying means of claim 1.

Claim 11 defines a method including the steps of restraining a bladder, initiating means for supplying pressurized

frequency irrespective of and greater than the inspiration and expiration breathing pattern of a person. Claim 10 further defines manual means for switching passing of air on and off at a rate corresponding with the inspiration and expiration breathing pattern of the person. For reasons adequately discussed, Claim 10 is nonobvious and patentable over the cited art.

As a result of a search report on a corresponding PCT application, Applicant has become aware of the following two patents and discloses them herein as a Supplementary Information Disclosure Statement:

PATENT NO.	PATENTEE	ISSUE DATE
2,263,844	Hammond	Nov. 25, 1981
PATENT NO.	**COUNTRY**	**ISSUE DATE**
2 556 213	France	Unknown

Both publications show respirators.

In view of the above, it is submitted that the pending claims are in condition for allowance. Reconsideration of the rejections is requested. Allowance of claims 1-7 and 9-13 at an early date is solicited.

Respectfully submitted,

Warren J. Warwick et al.

By their Attorneys,

Merchant, Gould, Smith, Edell,
Welter & Schmidt, P.A.
3100 Norwest Center
90 South Seventh Street
Minneapolis, Minnesota 55402
(612) 332-5300.

By Curtis B. Hamre
Curtis B. Hamre
Reg. No. 29,165

Plaintiff's Preliminary Claim Chart Alleging Infringement of the '263 Patent by Defendant's Medpulse 2000 Device

Elements of the infringed claims	Disclosed Structure in '263 Patent for means plus function elements	Corresponding Structure of Medpulse 2000
1. Oscillatory chest compression apparatus for a person, comprising:		The preamble is not a claim limitation. NOTE: Item numbers used in this chart are correspondingly labeled in the attached figures and drawings.
means for applying a force to the chest of said person, said force applying means including a bladder for receiving pressurized air; This element is written in means plus function language and is governed by 35 U.S.C. § 112 ¶6	Col. 1, ll. 49-53, 59-67 Col. 2, ll. 3-5, 53-60 Col. 3, ll. 12-21, 42-43, 50-52, 55-56 Col. 4, ll. 40-43, 54-68 Col. 5, ll. 1-17 Col. 6, ll. 4-12, 16-26, 47-50, 61-65 Col.7, ll. 7-36 Figs. 1-3	A bladder 6 is shown in Figures 12 and 13.
means for supplying a continuous regular pattern of pulses of said pressurized air to said bladder at a frequency irrespective of and greater than the breathing frequency of said person; This element is written in means plus function language and is governed by 35 U.S.C. § 112 ¶6	Col. 1, ll. 53-68 Col. 2, ll. 1-8, 54-68 Col. 3, ll. 1-39, 56-65 Col. 4, ll. 1-18, 38-53 Col. 5, ll. 3-68 Col. 6, ll. 1-35, 45-68 Col. 7, ll. 1-36 Fig. 1-4	The Medpulse 2000 uses a bellows 2 to send pulses of air through a tube 4 to a bladder 6 which is constrained against the body by a shell 8. Figures 1, 2, 4, 5, 9, 10, 12-14
means for venting said pressurized air from said bladder; and This element is written in means plus function language and is governed by 35 U.S.C. § 112 ¶6	Col. 1, ll. 55-58, 63-67 Col. 2, ll. 56-63 Col. 3, ll. 9-13, 42-68 Col. 4, ll. 10-14 Col. 5, ll. 6-27, 64-68 Col. 6, ll. 17-23, 46-50	A manual flow valve 10 allows pressurized air to vent from the bladder 6. Figures 3, 6, 7, 11.

Elements of the infringed claims	Disclosed Structure in '263 Patent for means plus function elements	Corresponding Structure of Medpulse 2000
	Col. 7, ll. 9-10, 16-19, 26-36	
means for controlling said pressurized air in said bladder so that the pressure therein can be increased and decreased in correspondence with the expiration and inspiration breathing frequency of said person wherein said force is applied by said applying means at the pulse frequency of said supplying means with greater impact when said controlling means allows increased air pressure in said bladder and with lessor impact when said controlling means allows decreased air pressure in said bladder. This element is written in means plus function language and is governed by 35 U.S.C. § 112 ¶6	Col. 1, ll. 49-68 Col. 2, ll. 1-8, 56-68 Col. 3, ll. 30-65 Col. 4, ll. 4-29 Col. 5, ll. 10-63 Col. 6, ll. 3-27, 45-68 Col. 7, ll. 1-36 Figs. 1-4	A control knob 11 operably manipulates the size of an orifice created and defined by manual flow valve 10, thereby allowing various flow rates of pressurized air to vent from the bladder 6. Figures 3, 6, 7, 11, 13-15.
2. Apparatus in accordance with claim 1 wherein said force applying means also includes a shell which said person wears to limit outward expansion of said bladder so that said bladder forces inwardly on said person's chest.		The Medpulse 2000 has a shell 8 which a patient wears to limit outward expansion of bladder 6 so that bladder 6 forces inwardly on the patient's chest. Figures 12-14.
3. Apparatus in accordance with claim 1 wherein said pulse supplying means includes a primary bellows;		The Medpulse 2000 has a primary bellows 2a for supplying pulses. Figures 1, 2, 5, 9, 10.

Elements of the infringed claims	Disclosed Structure in '263 Patent for means plus function elements	Corresponding Structure of Medpulse 2000
first means for communicating air between said primary bellows and said bladder; This element is written in means plus function language and is governed by 35 U.S.C. § 112 ¶6	Col. 2, ll. 3-5 Col. 5, ll. 64-65 Col. 6, ll. 45-50	Tube 4 communicates air between the primary bellows 2a and the bladder 6. Figures 12-14.
means for providing air to said primary bellows; and This element is written in means plus function language and is governed by 35 U.S.C. § 112 ¶6	Col. 6, ll. 3-68 Col. 7, ll. 1-36 Fig. 3	Air flows through one-way valves 12 to primary bellows 2a. Figures 1, 10.
primary means for reciprocating said primary bellows between expansion and contraction configurations thereby creating pulses of pressurized air. This element is written in means plus function language and is governed by 35 U.S.C. § 112 ¶6	Col. 5, ll. 57-63 Col. 6, ll. 27-44, 66-68 Col. 7, ll. 7-13, 20-36	A motor 14 is used to reciprocate the primary bellows 2a between expansion and contraction configurations thereby creating pulses of pressurized air. Figures 2, 4, 5, 7, 10, 11.

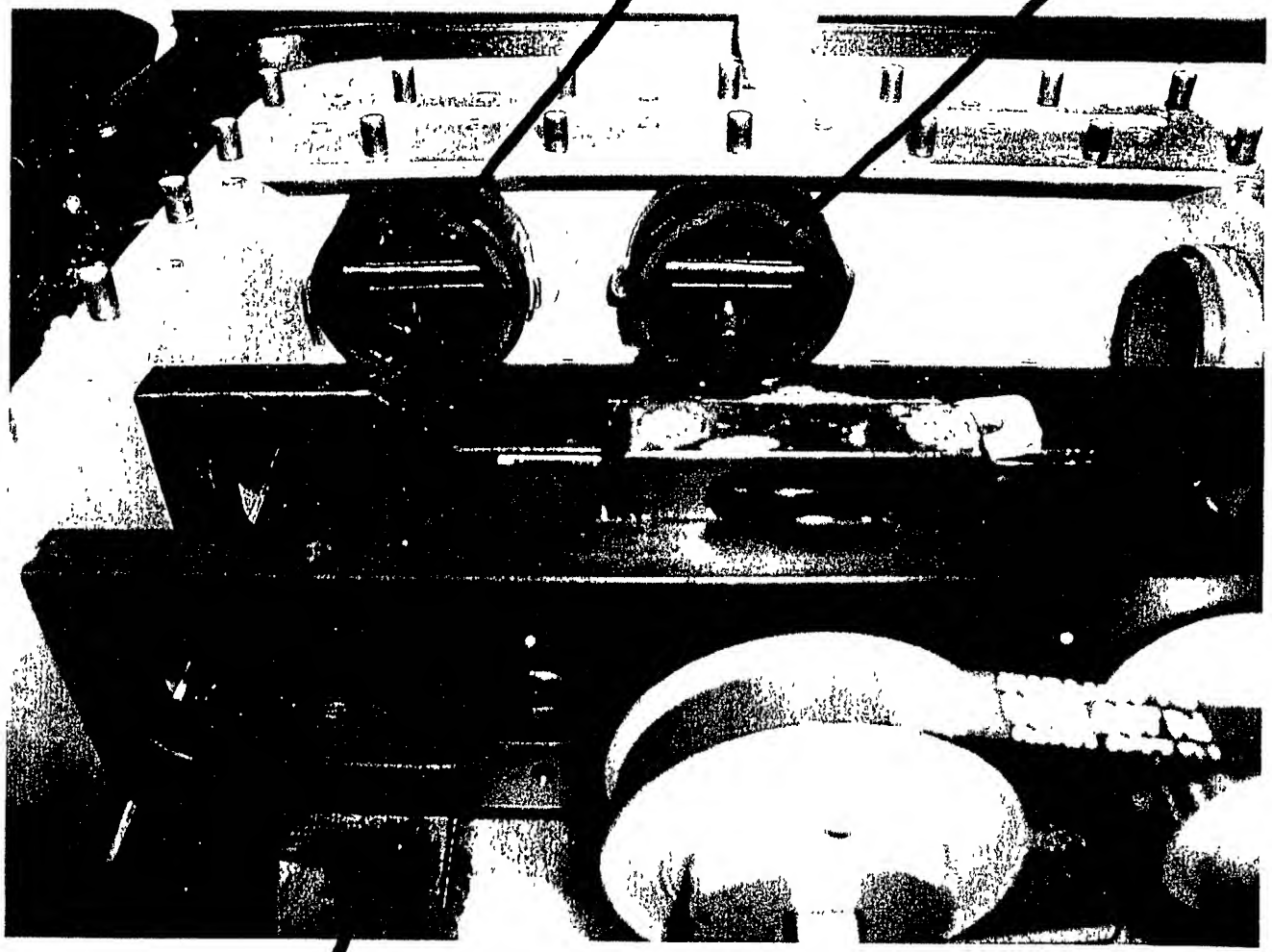


FIG 1

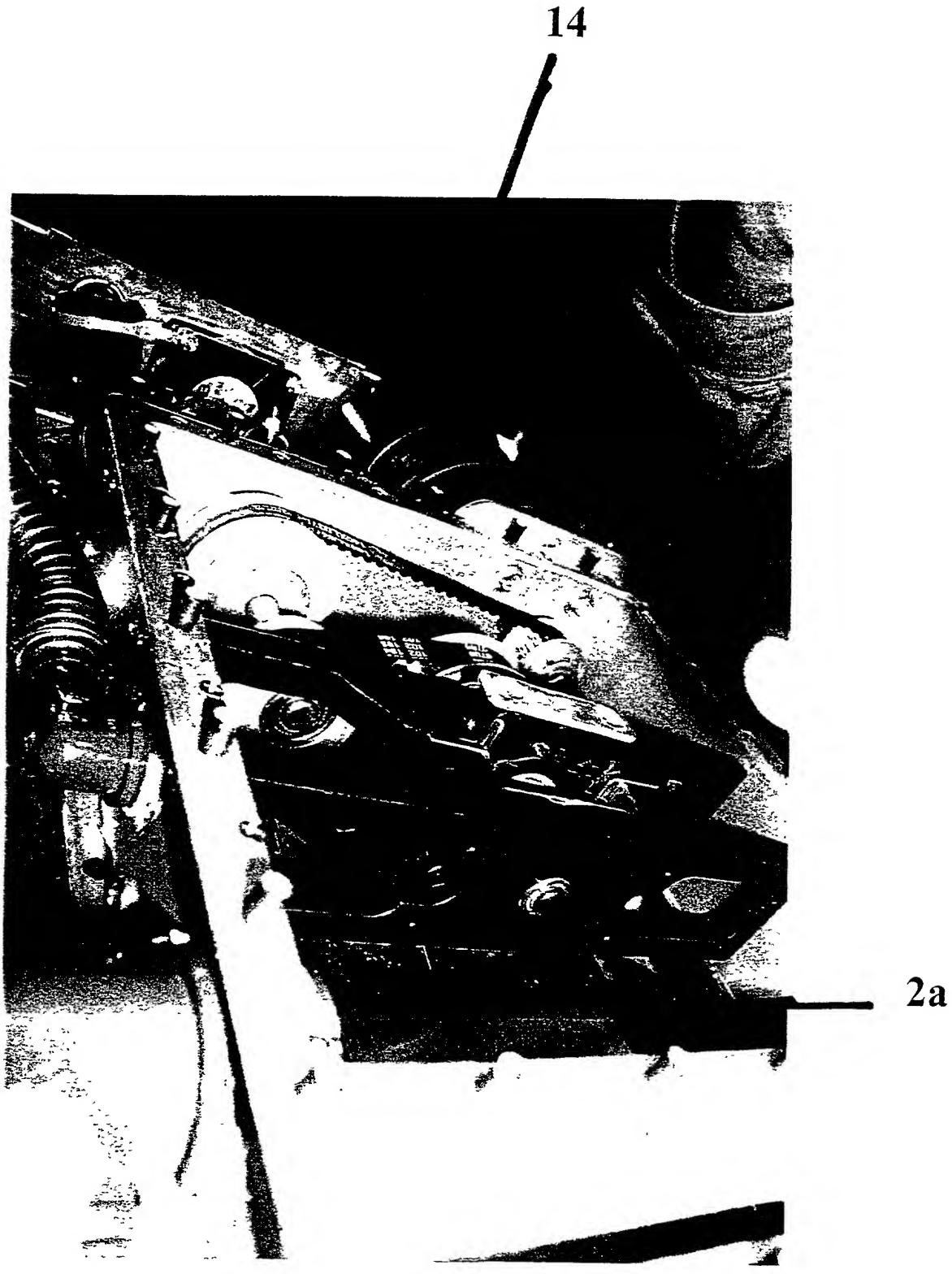


FIG 2

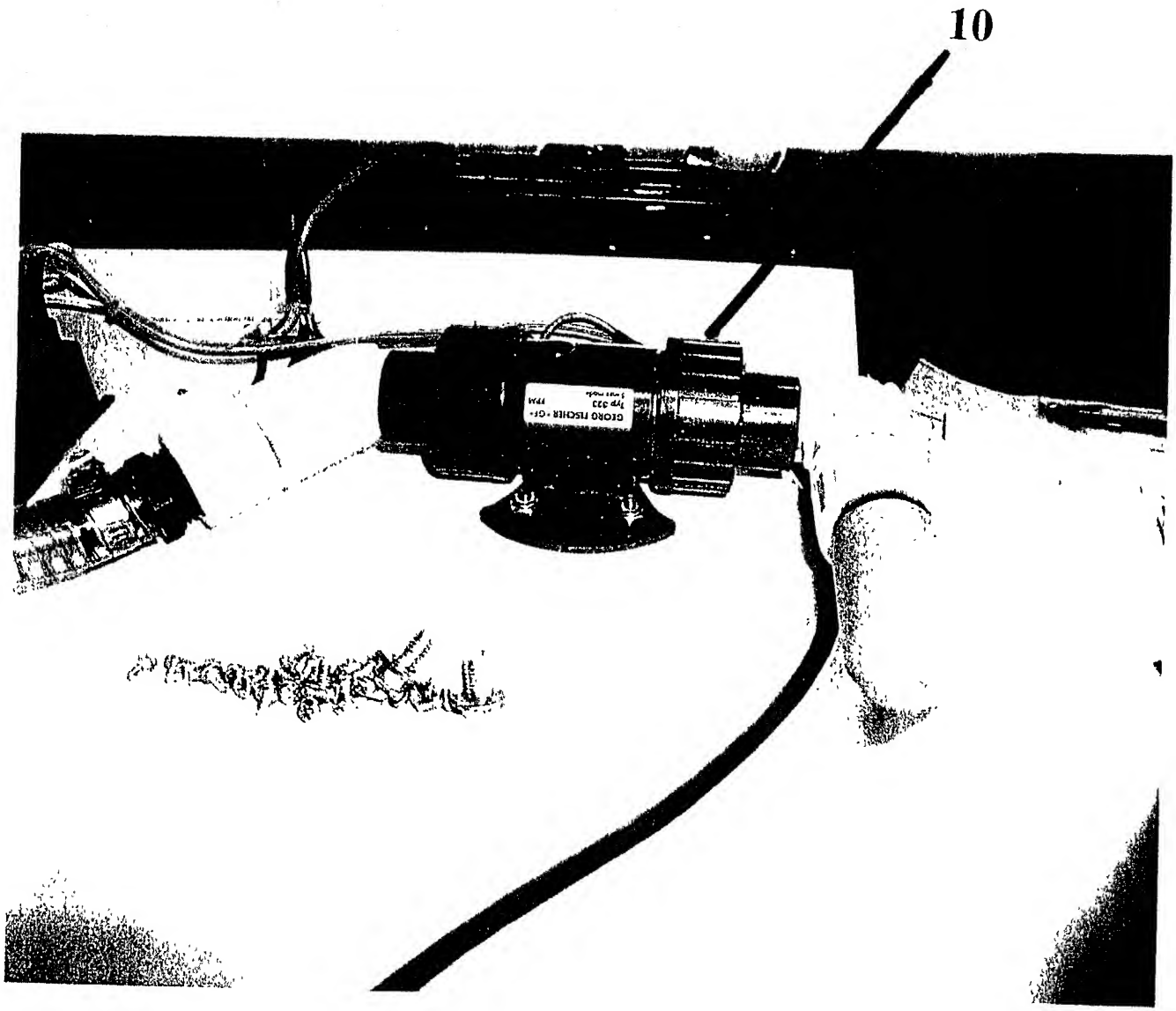


FIG 3

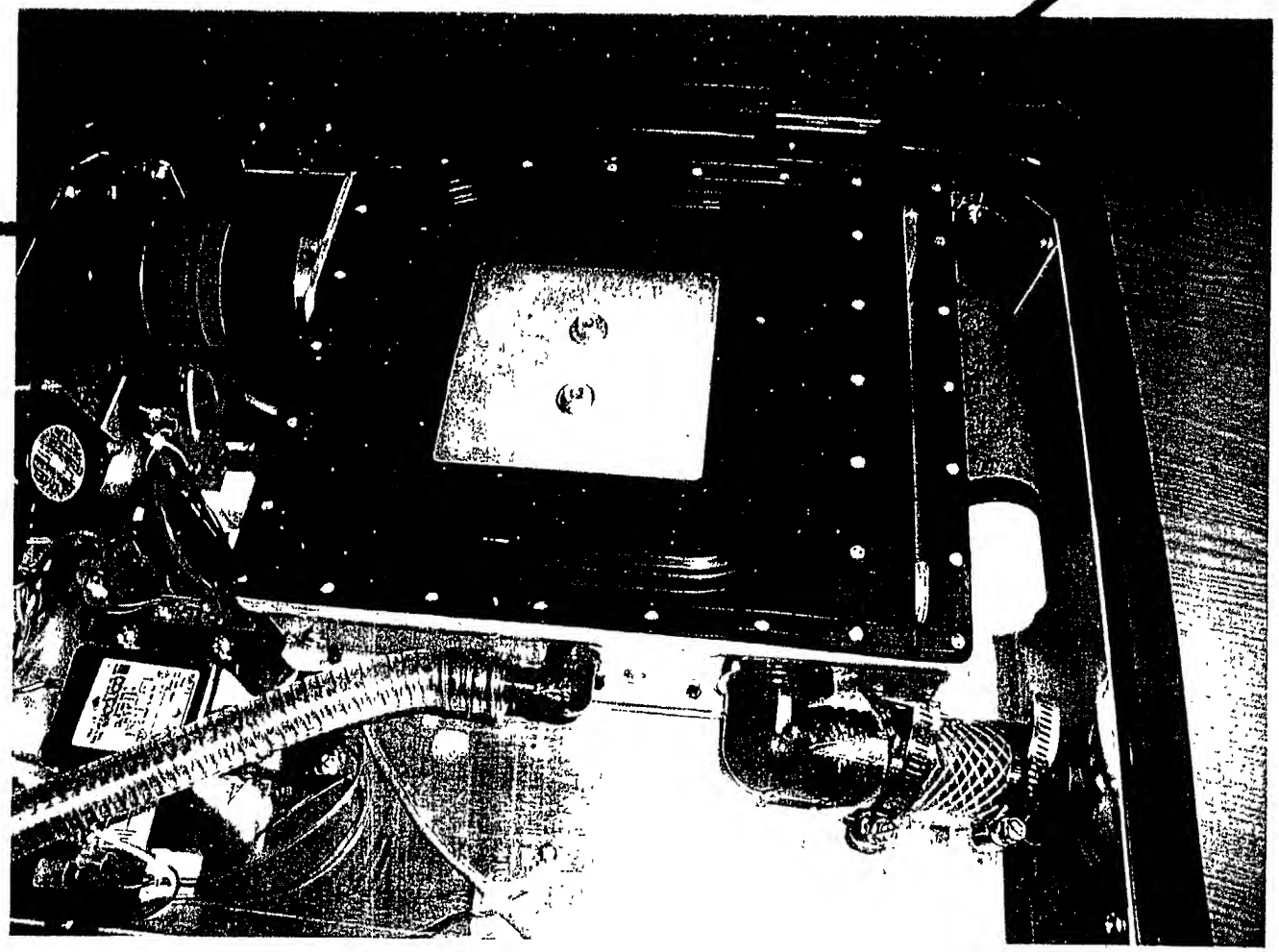


FIG 4

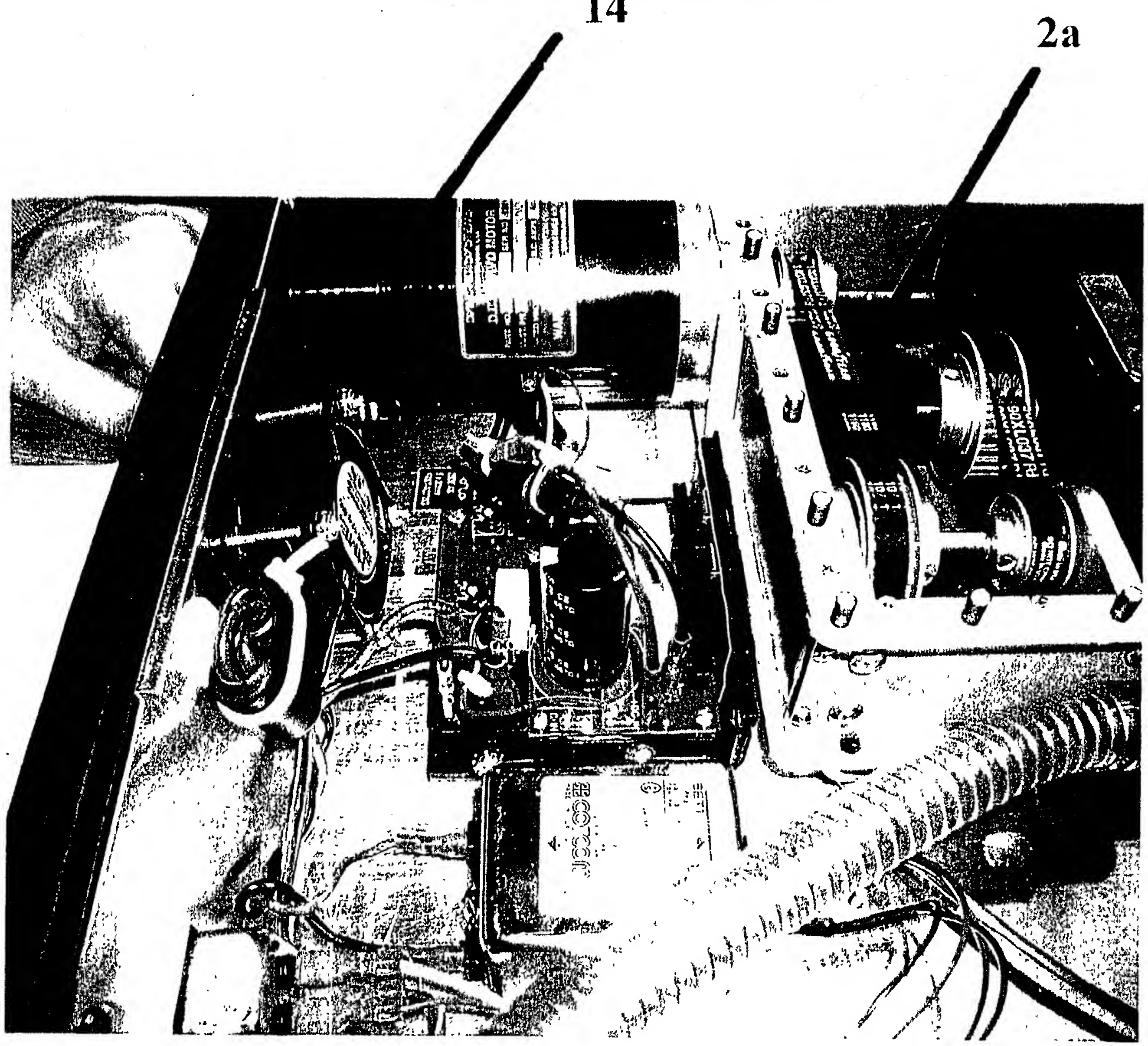


FIG 5

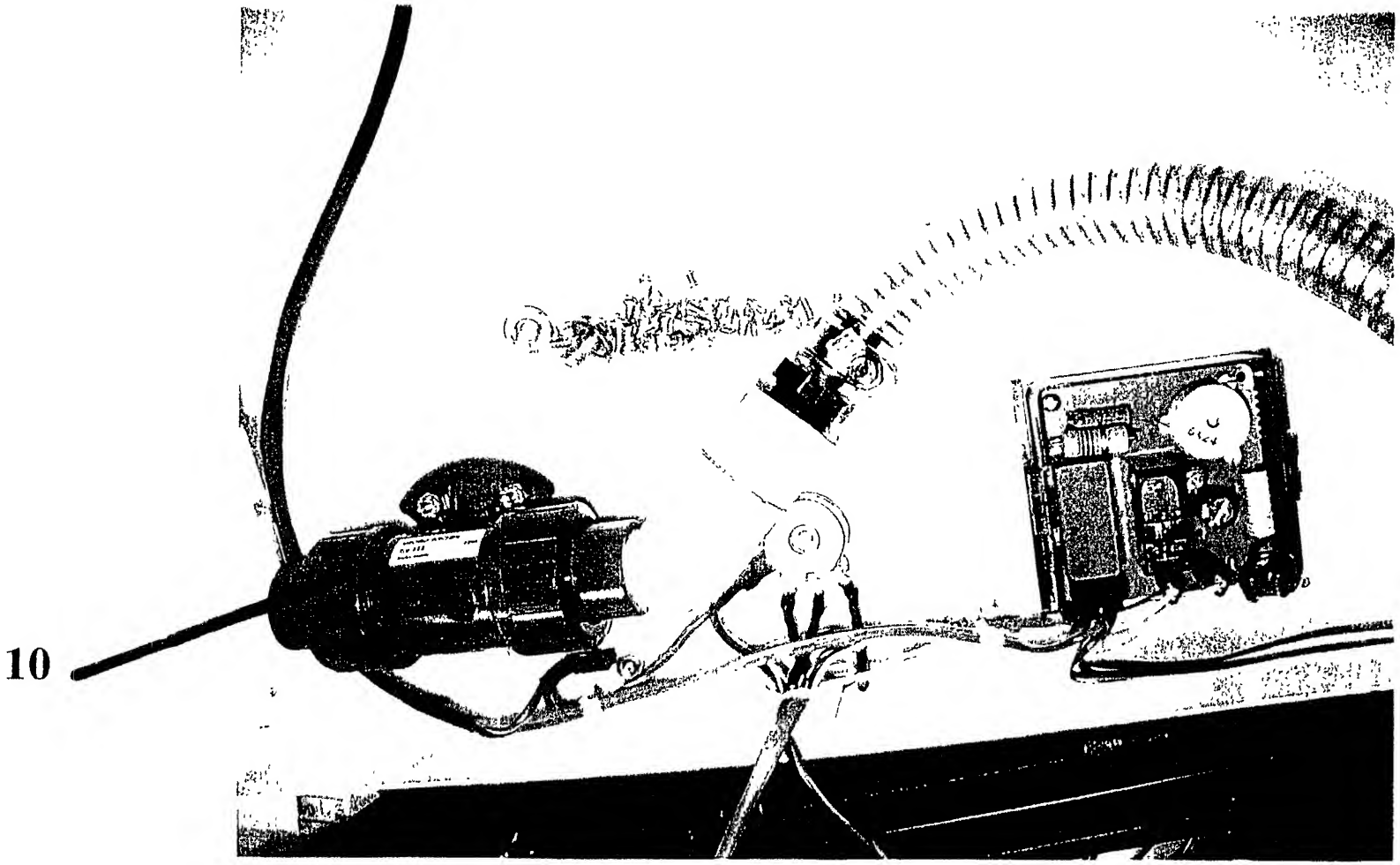


FIG 6

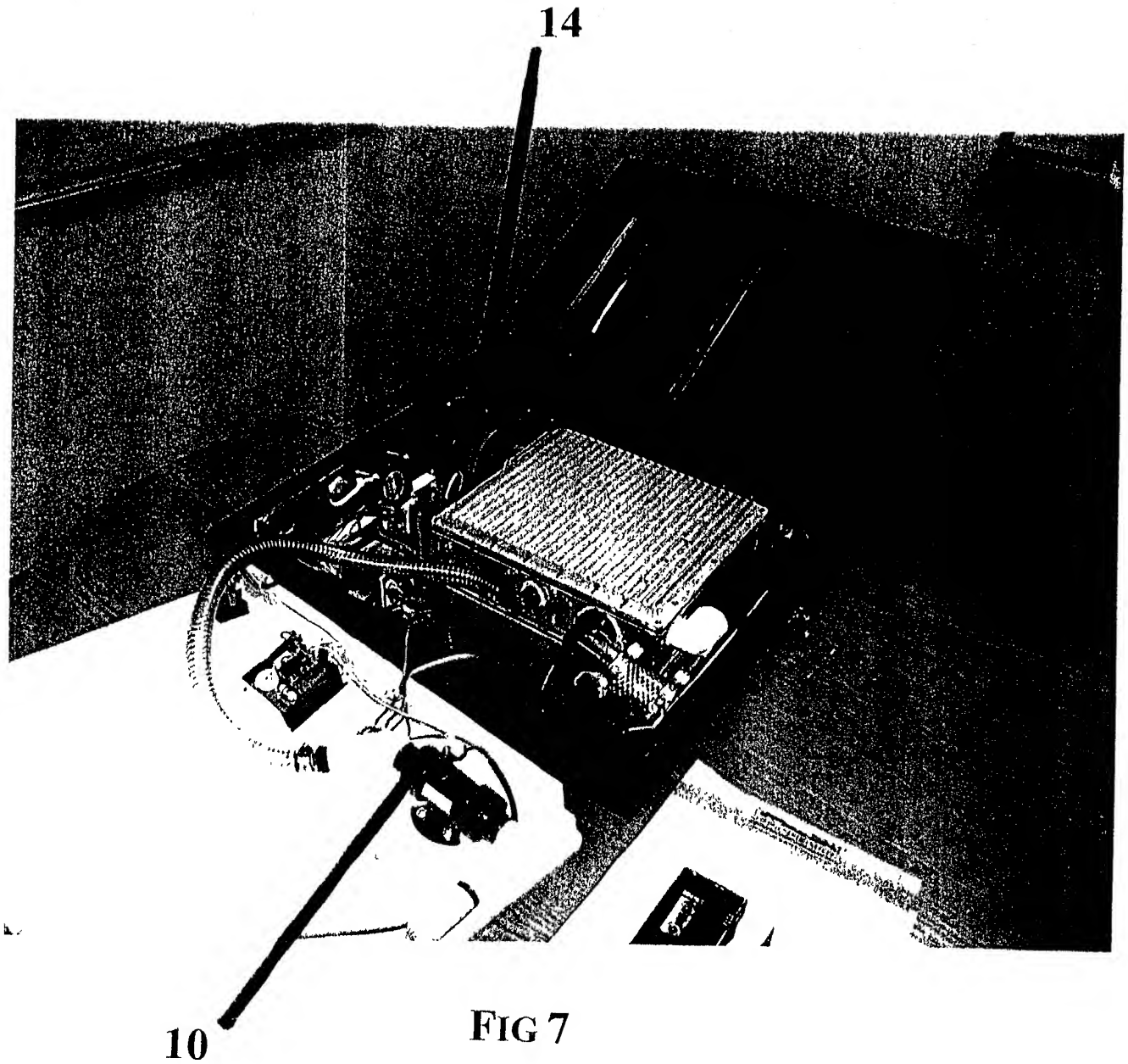


FIG 7

FIG 8

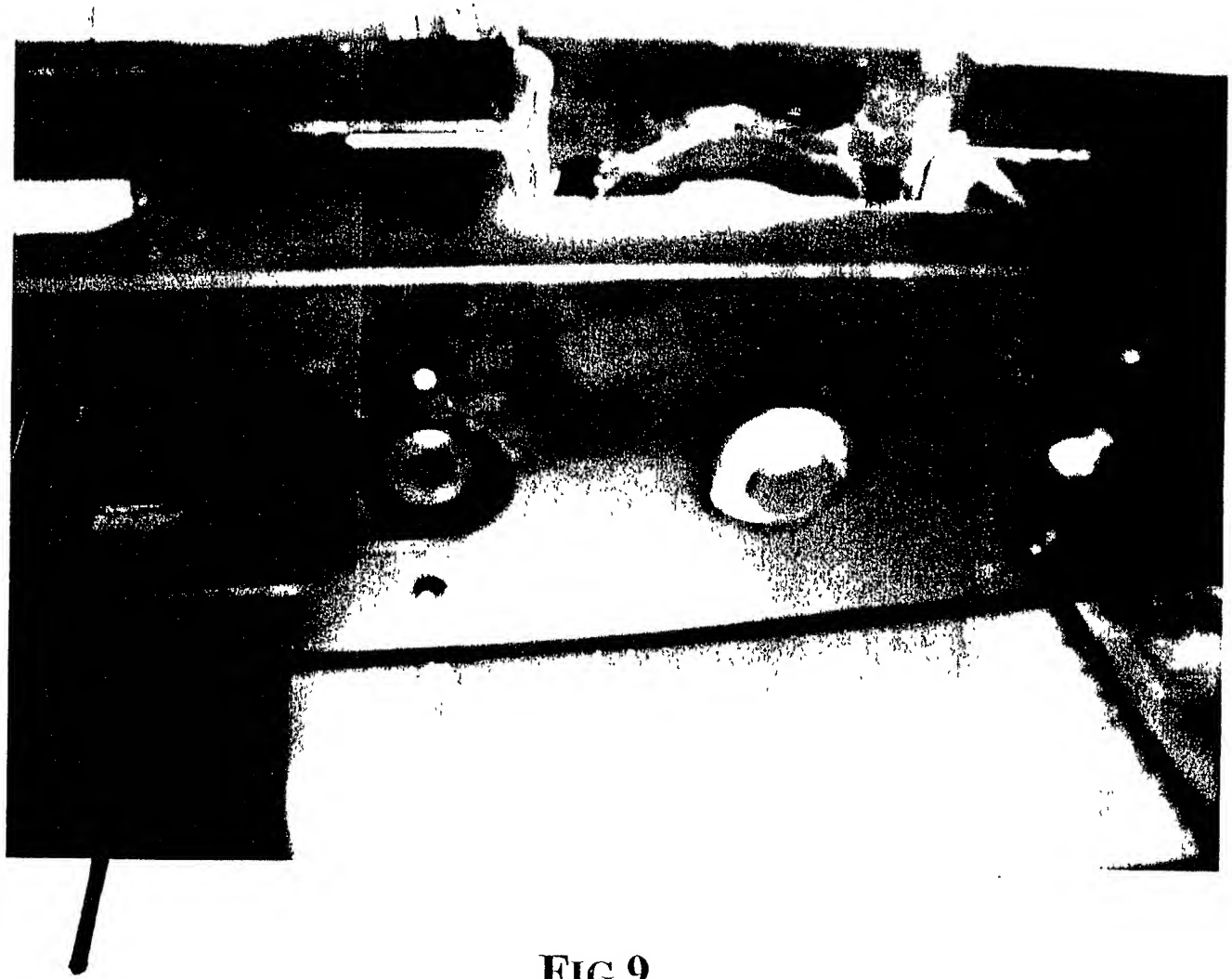


FIG 9

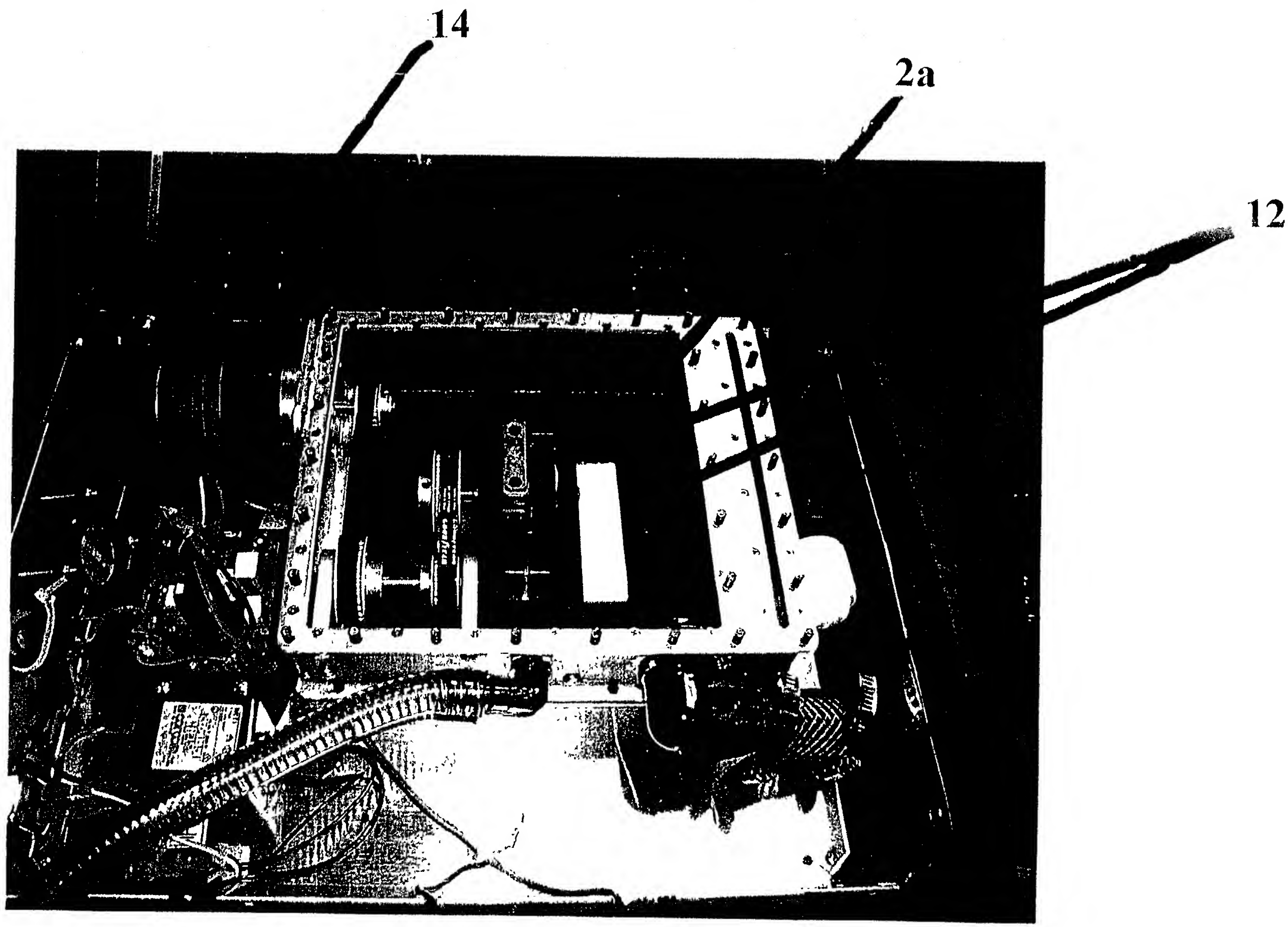


FIG 10

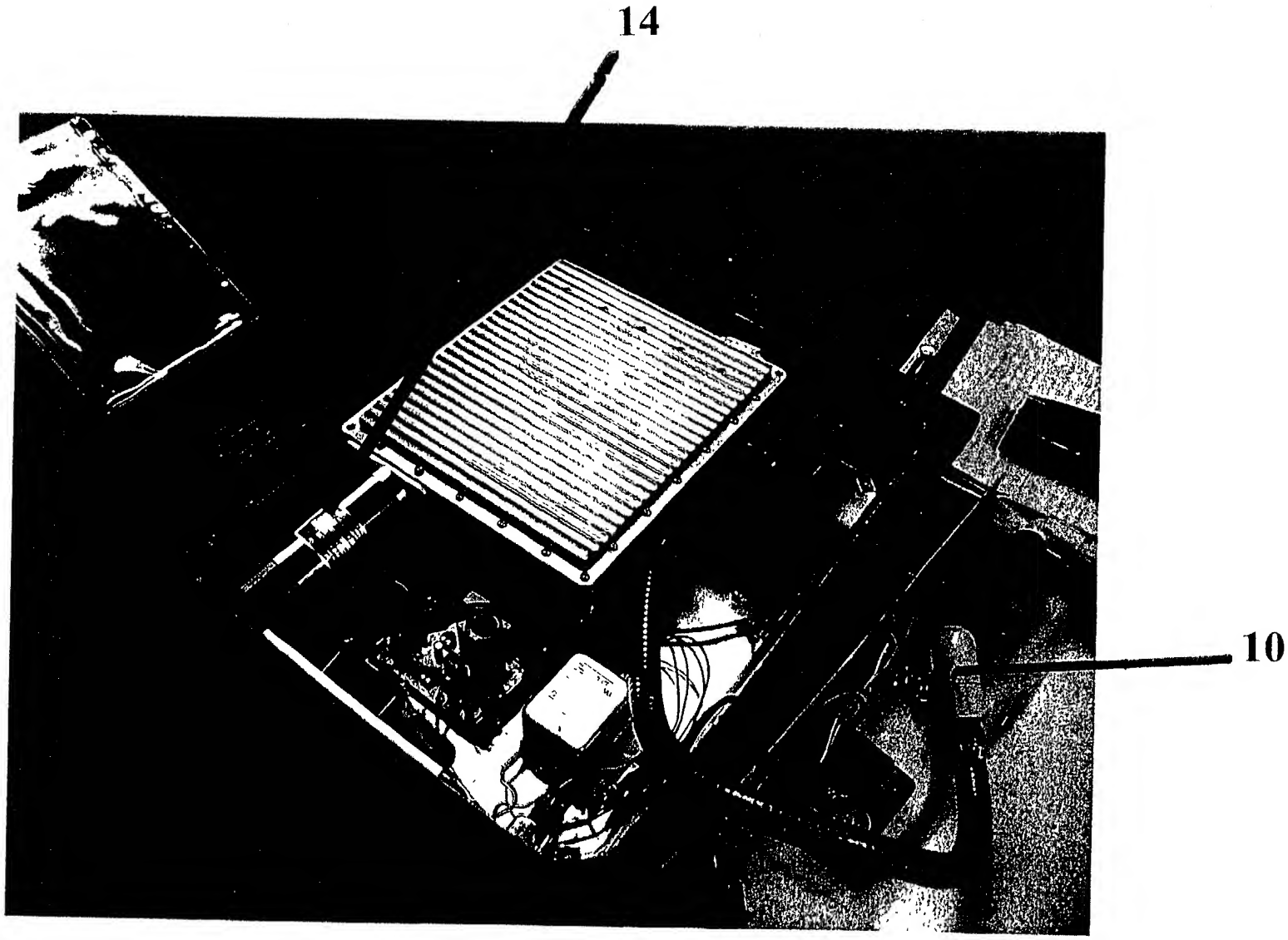


FIG 11

FIG 12

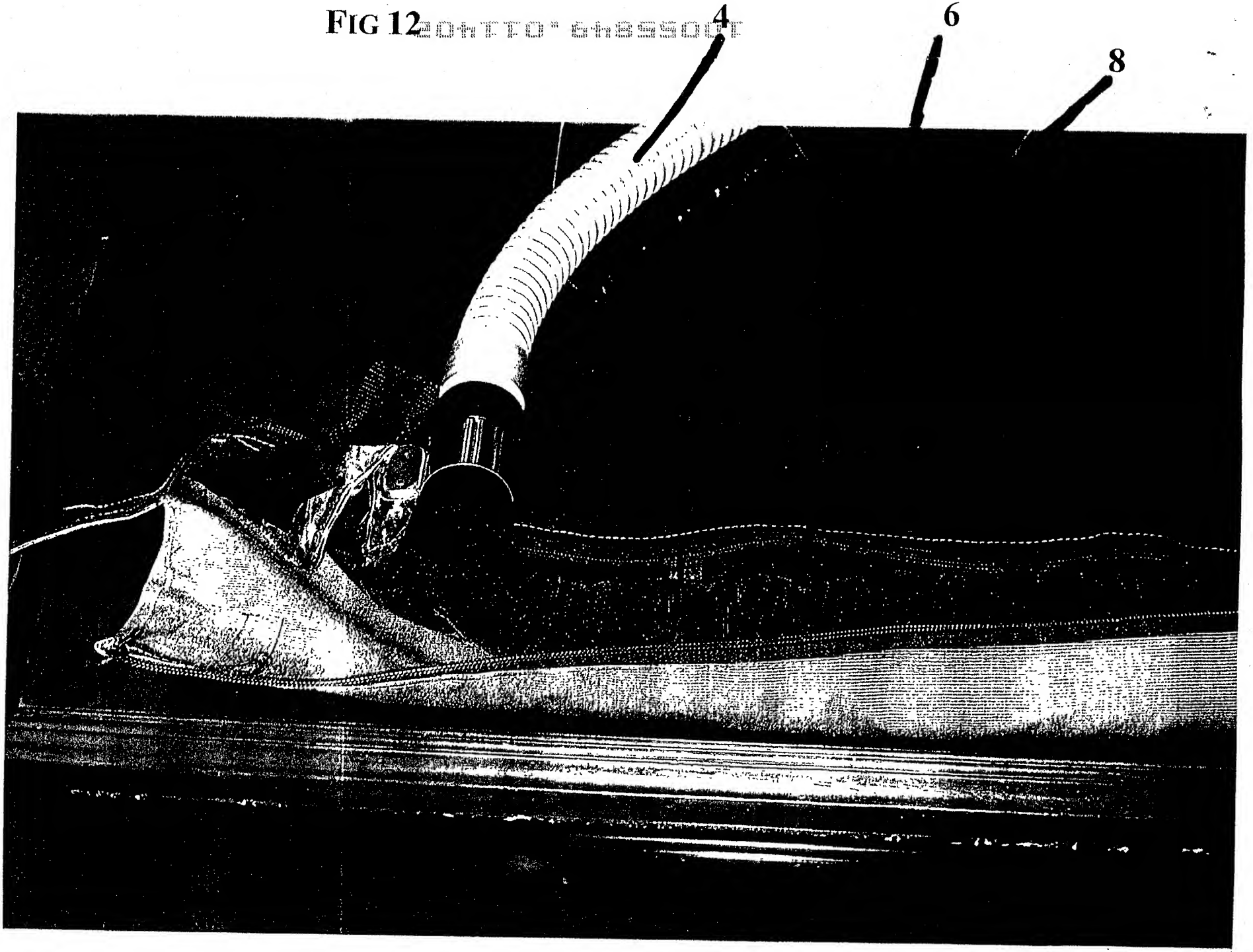


FIG 13

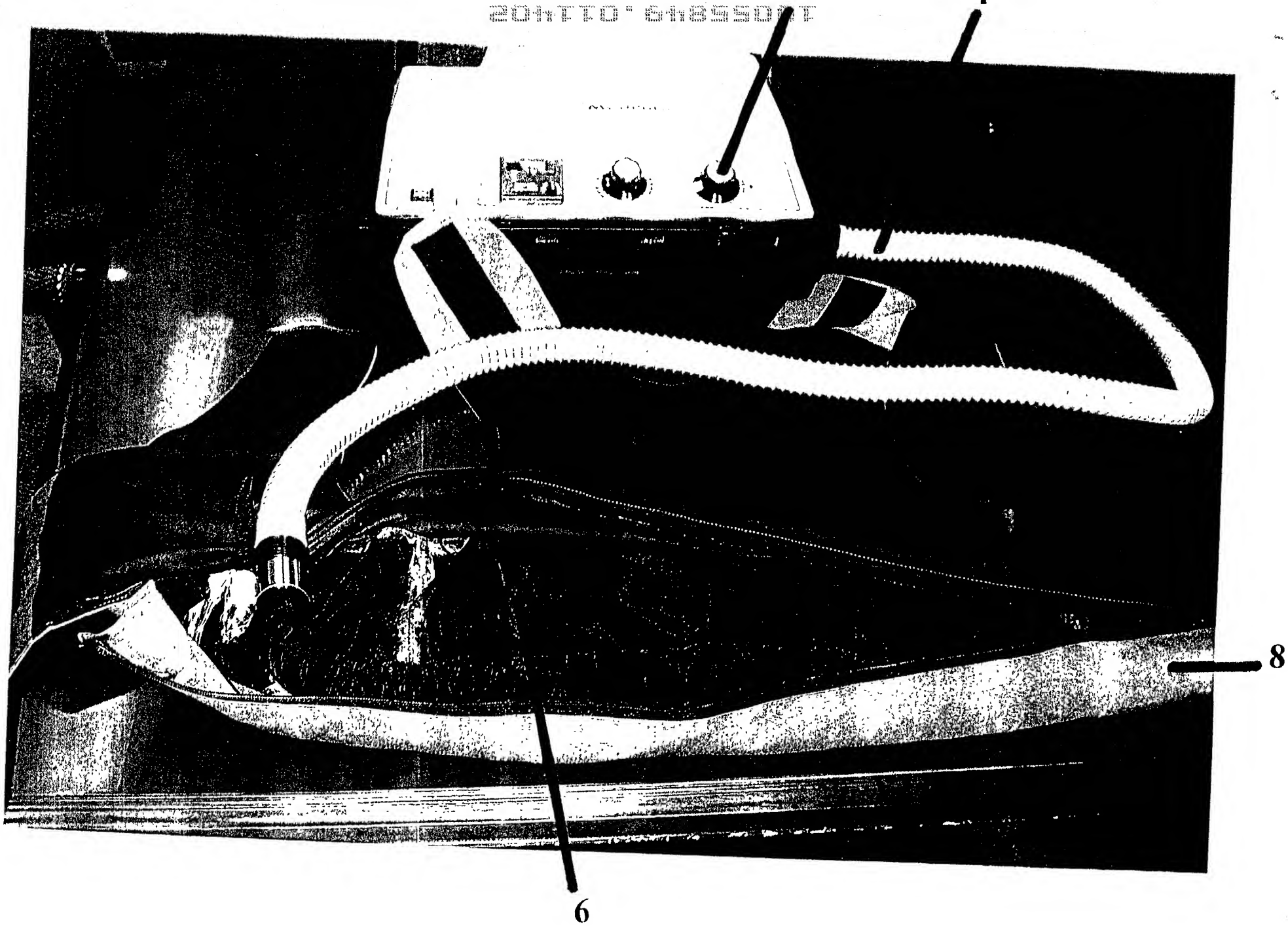


FIG 14

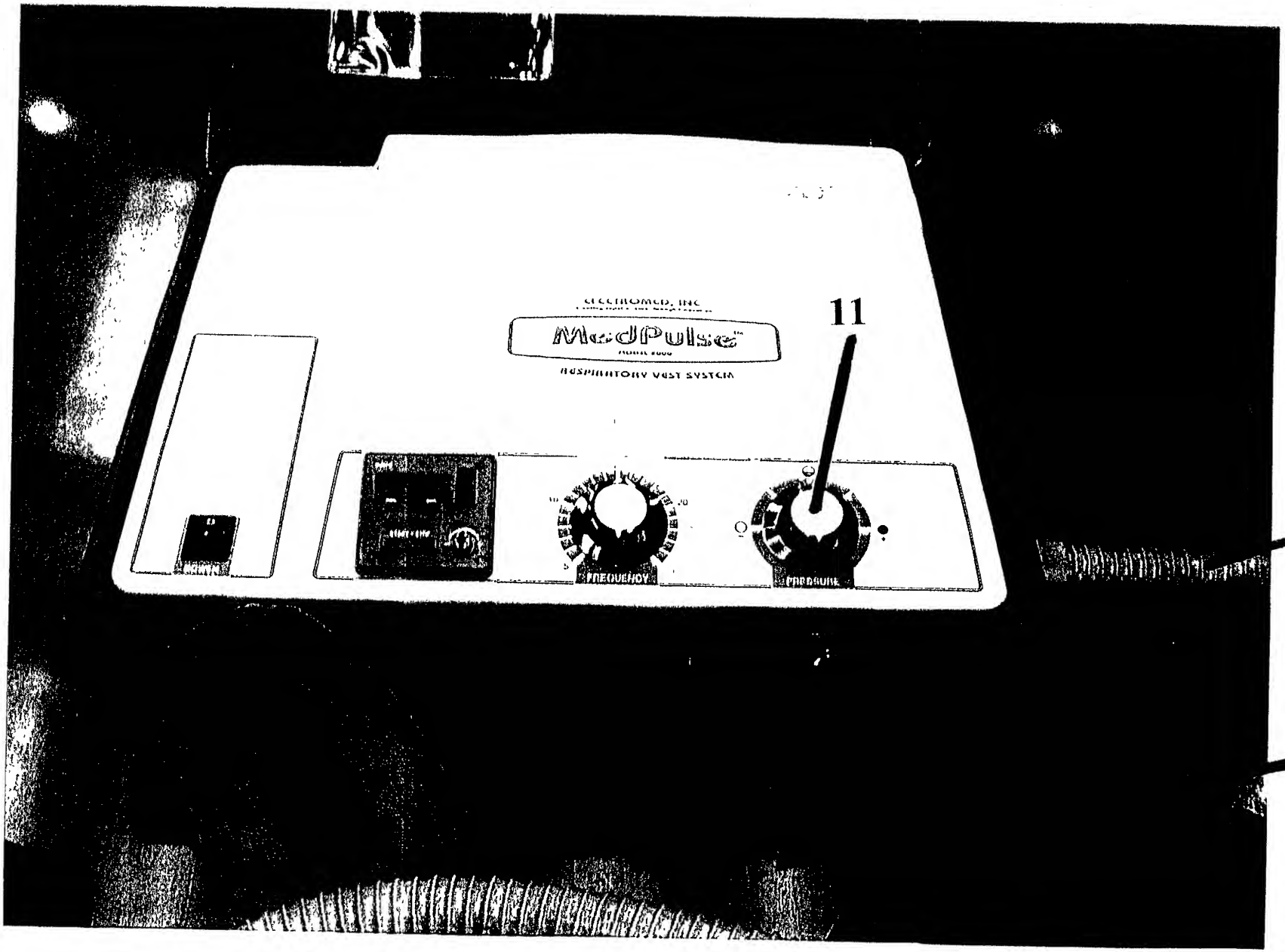

ELECTROMED, INC
MedPulse
RESPIRATORY VEST SYSTEM
FREQUENCY
PRESSURE
11
4
8

FIG 15

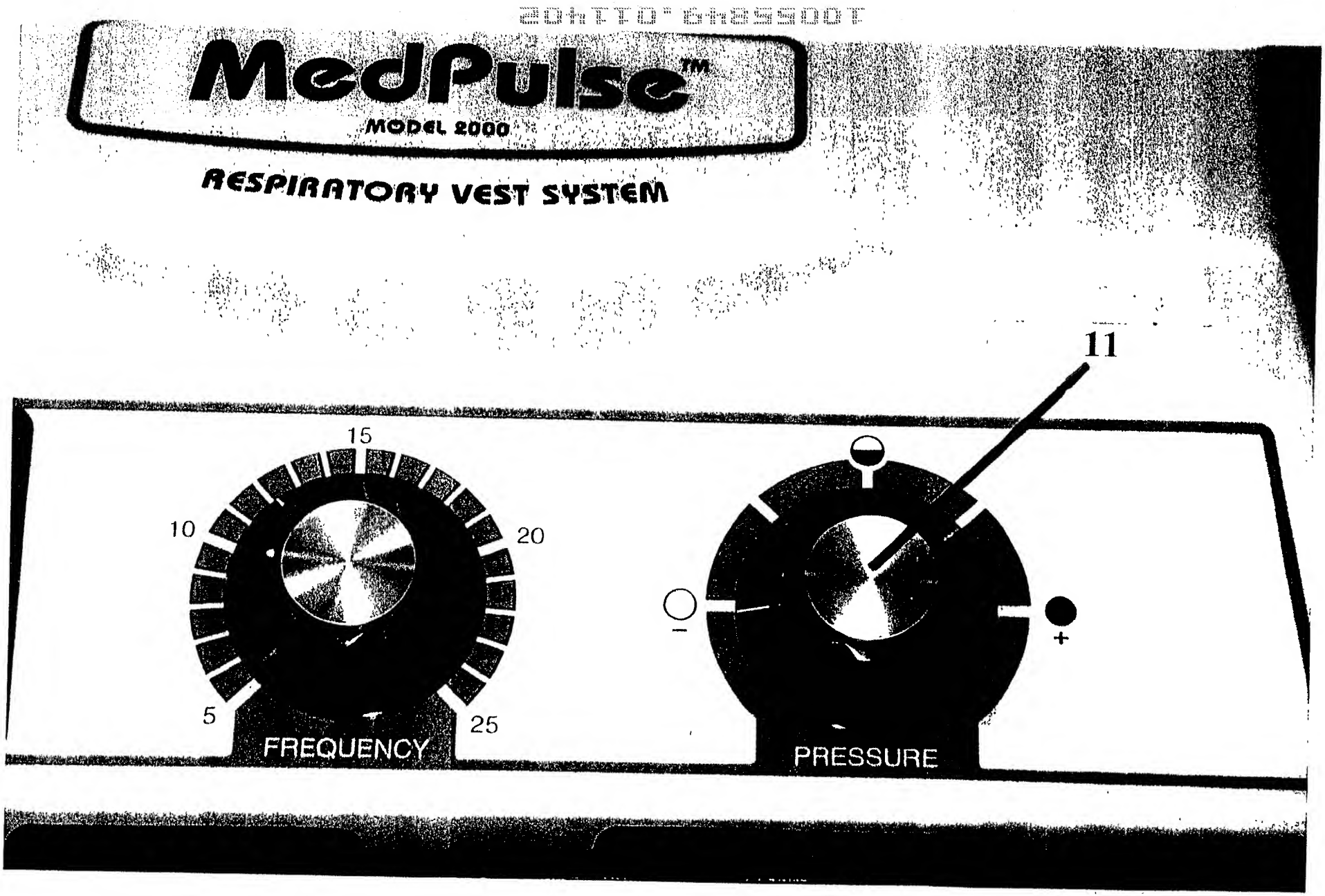
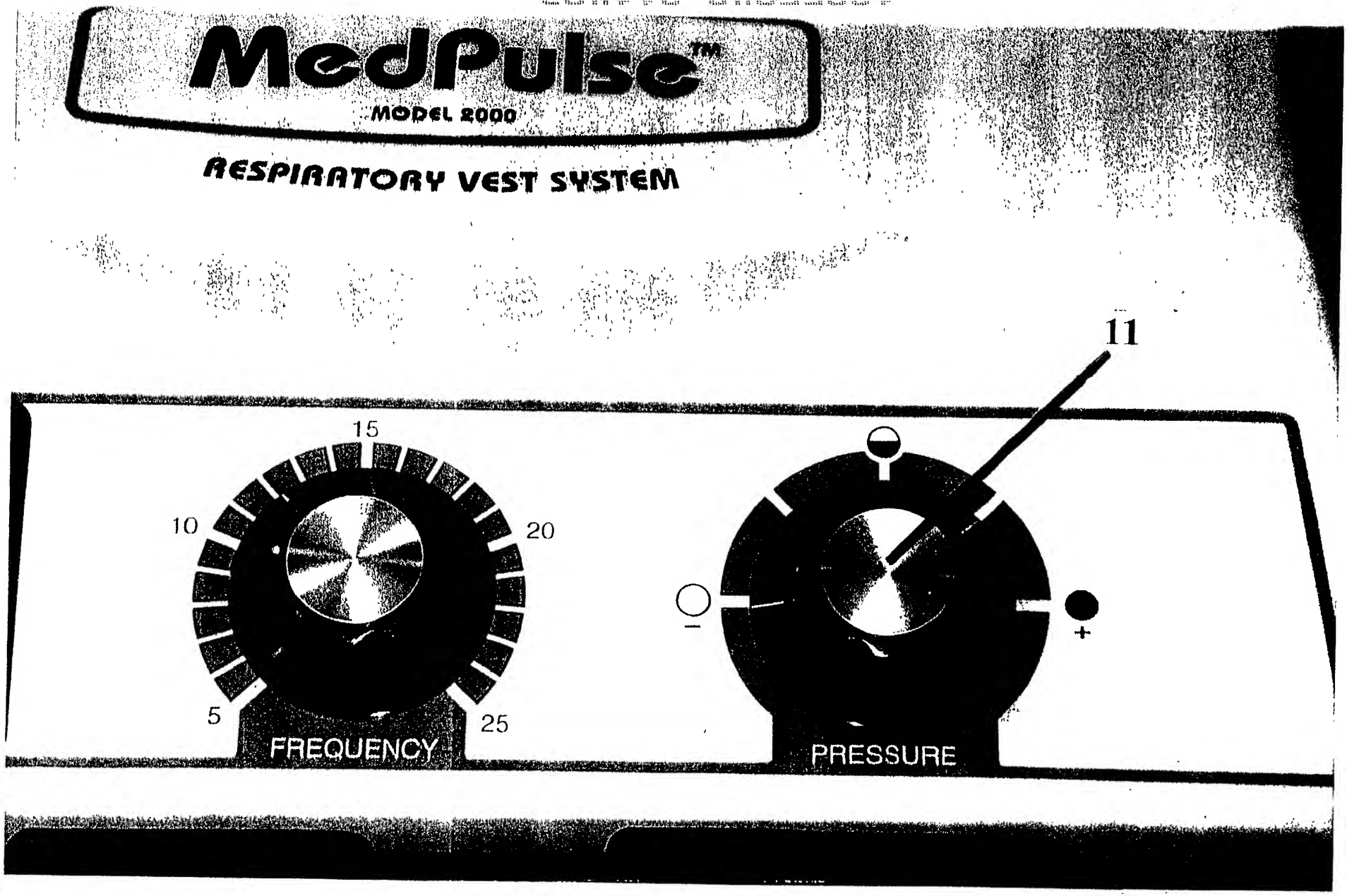

MedPulse™
MODEL 2000
RESPIRATORY VEST SYSTEM
11
15
10
20
5
25
FREQUENCY
PRESSURE
−
+

FIG 15


MedPulse™
MODEL 2000
RESPIRATORY VEST SYSTEM
11
15
10
20
5
25
FREQUENCY
PRESSURE
−
+

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	Case Number: 00-2646 DWF/SRN **PROPOSED ORDER FOR LEAVE TO AMEND COMPLAINT**

Pursuant to Federal Rule of Civil Procedure 15(a), this Court hereby **GRANTS** Plaintiff American Biosystems, Inc. leave to amend the Complaint to add a court for infringement of U.S. Patent No. 4,838,263 ("the '263 Patent").

Dated _____, 2001

_____
Magistrate Judge Susan R. Nelson
United States District Court

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

American Biosystems, Inc.,

Plaintiff,

v.

Civil Action No.

00-2646 DWF/SRN

Electromed, Inc.,

Defendant.

DEFENDANT ELECTROMED, INC.'S MEMORANDUM IN OPPOSITIION TO PLAINTIFF AMERICAN BIOSYSTEMS' MOTION TO AMEND THE COMPLAINT

Plaintiff, American Biosystems, Inc.'s ("ABI") motion to amend the Complaint should be denied as it fails to join a party indispensable under Rule 19 of the Federal Rules of Civil Procedure.

INDISPENSABLE PARTY

The proposed Amended Complaint fails to join an indispensable party, the Regents of the University of Minnesota ("University"). The entire right, title and interest of U.S. Patent No. 4,838,263 ("the '263 patent") is in the University. Plaintiff does not allege that they own the '263 patent.

RIGHTS OF UNIVERSTY

The absence of the University impairs the University's ability to protect their property interest in the '263 patent and compressive thoracic technology. The validity of the '263 patent will be a major issue in the lawsuit. Inequitable conduct and fraud on the U.S. Patent and Trademark Office in obtaining the '263 patent are additional factors in the lawsuit. The scope and content of the claims of the '263 patent effects the property rights of the University. An application for reexamination of the '263 patent

filed by Electromed is the obligation of the University to prosecute. These interests of the University will not be protected if it is not a party or a party to a separate lawsuit.

RIGHTS OF ELECTROMED

The University must be joined as a party to the Amended Complaint because in the absence of the University, Electromed cannot obtain complete relief. The University's potential claim of infringement of the '263 patent is not extinguished by the Amended Complaint. There is nothing from precluding the University from filing a civil action for patent infringement by Electromed. Inequitable conduct and fraud on the U.S. Patent and Trademark Office in obtaining the '263 patent by the University are the basis of Electromed's damages and attorneys fees which ABI would most likely not assume. The University is liable to Electromed for their conduct that predicates harm to Electromed.

NON-EXCLUSIVE LICENSE

ABI alleges that they are the exclusive licensee of the '263 patent. The license agreement between ABI and the University is included in ABI's Exhibit 3. ABI was not granted an exclusive license. The University retained an irrevocable, non-exclusive and non-transferable right to practice for their own non-commercial educational and research purposes the technology and University improvements (Page 7, lines 21-25). Also, all government funded research includes a royalty-free right for the government to use any inventions for government purposes (Page 20, lines 13-18). Since all of the rights to make, use and sell the technology which includes the '263 patent have not been licensed to ABI, the agreement is a non-exclusive license. A non-exclusive license does not have a right to sue for infringement of a patent in absence of the owner of the patent.

SCHEDULING ORDER AND PARTIES

The present Scheduling Order is limited to ABI, Electromed and U.S. Patent No. 6,036,662 ("the

'662 patent"). The addition of the '263 patent, additional parties and attorneys will require a new Scheduling Order. Additional defenses and counterclaims and cross-claims will expand needed discovery and witnesses. Trial time may be extended to 30 or more days. The addition of the '263 patent will delay the entire proceeding and consume substantial judicial time and effort. Since at least one of the parties to the case is different, the '263 patent is not related to the '662 patent, and a new Scheduling Order is needed, the motion to amend the Complaint should be denied.

VAGUE ALLEGATION OF INFRINGEMENT OF THE '263 PATENT

Paragraph 19 of the Amended Complaint alleges that Electromed is directly infringing claims of the '263 patent by making, offering to sell and selling chest compression devices with oscillatory air pressure pulses exerted on the body. A more definite statement is required to provide Electromed with a basis for this infringement allegation. The use of chest compression devices with oscillatory air pressure pulses is old in the art. G.A. Williams in U.S. Patent No. 1,898,652 granted February 21, 1933 (ABI Exhibit 6) discloses a chest compression device that applies oscillatory air pressure pulses to the body of a person. The allegation of patent infringement should include at least the allegation that the patented invention and the elements thereof are being infringed.

Infringement is the unauthorized making and selling of a patented invention. 35 U.S.C. §271(a). Infringement is determined by comparing the accused device to the claims of the patent. Literal infringement exists when the accused device embodies each element described in a claim of the patent. *See, e.g. Builders Concrete, Inc. v. Bremerton Concrete Products Co.,* 757 F.2d 255, 257 (Fed. Cir. 1985).

There is no allegation in the Amended Complaint that the Electromed device has structure that embodies each element described in a claim or claims of the '263 patent. A more definitive statement is

in order to respond to the allegations of infringement of the Amended Complaint. The motion to amended the Complaint should be denied as the allegation of infringement of the '263 patent is so vague that it fails to state a claim of patent infringement.

In view of the above noted defects in the proposed Amended Complaint, Defendant submits that the motion to amend the Complaint be denied.

Respectfully submitted,

Dated: May 29, 2001

BARTZ & BARTZ, P.A.

By Richard O. Bartz

Richard O. Bartz, #5174
Richard J. Bartz, #166364
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435-1983
Telephone: (952) 920-3959
Facsimile: (952) 920-6494

Attorneys for Defendant
Electromed, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

American Biosystems, Inc.,

Plaintiff,

v.

Electromed, Inc.,

Defendant.

Civil Action No.

00-2646 DWF/SRN

DEFENDANT ELECTROMED, INC.'S NOTICE OF MOTION AND MOTION FOR SETTLEMENT CONFERENCE AND POSTPONEMENT OF MOTION TO AMEND COMPLAINT

TO: Plaintiff above-named and their attorney; Cyrus A. Morton, Oppenheimer, Wolff & Donnelly, 3300 Plaza VII Building, 45 South Seventh Street, Minneapolis, Minnesota 55402

NOTICE OF MOTION

PLEAE TAKE NOTICE that, pursuant to Rule 16(a) of the Federal Rules of Civil Procedure, Defendant, Electromed, Inc. ("Electromed"), by and through their counsel, will bring the following motion before the Honorable Susan R. Nelson, Magistrate Judge of the United States District Court, at a time determined by the Court.

MOTION

Pursuant to Rule 16(a) of Federal Rules Civil Procedure, Electromed moves that the Court direct the attorneys for the parties and persons with authority to settle this litigation to (1) meet within the next fifteen (15) days for settlement negotiations, (2) appear before the Court for a conference for the purpose of facilitating the settlement of the case, and (3) postpone the motion to amend the Complaint or postpone the decision of the motion to amend the Complaint

until after the settlement conference.

This motion is made on the basis of settlement proposals, files, records and proceedings herein.

Dated: May 29, 2001

BARTZ & BARTZ, P.A.

By [signature]

Richard O. Bartz, #5174
Richard J. Bartz, #166364
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435-1983
Telephone: (952) 920-3959
Facsimile: (952) 920-6494

Attorneys for Defendant Electromed, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

American Biosystems, Inc.,

Plaintiff,

v.

Civil Action No.

00-2646 DWF/SRN

Electromed, Inc.,

Defendant.

DEFENDANT ELECTROMED, INC.'S MEMORANDUM IN SUPPORT OF MOTION FOR SETTLEMENT CONFERENCE AND POSTPONEMENT OF MOTION TO AMEND COMPLAINT

SETTLEMENT OF CASE

Defendant, Electromed, Inc. ("Electromed") has since the commencement of this litigation been willing to negotiate a settlement of all disputes with ABI. Electromed's desire to negotiate a settlement has been communicated to the attorneys of Plaintiff, American Biosystems, Inc. ("ABI") at the Scheduling Conference with the Court and restated in correspondence with ABI's counsel (Exhibit 3). A letter dated May 8, 2001 with a proposed Settlement Agreement was forwarded to ABI (Exhibit 1). ABI in a response dated May 15, 2001 to the proposed Settlement Agreement stated that "[w]e are interested in continuing settlement discussions and are in the process of preparing our own settlement offer which we will make in due course" (Exhibit 2). It was noted that ABI did not accept nor reject Electromed's proposed Settlement Agreement. Electromed requested on May 23, 2001 that ABI expedite their settlement offer to conclude the litigation without further adversary proceedings (Exhibit 3). Electromed also suggested that ABI's Motion to Amend the Complaint be postponed for 30 days and that settlement

discussions proceed in the next 30 days. ABI on May 25, 2001, rejected Electromed's offer, which Electromed interprets as the proposed Settlement Agreement (Exhibit 4). ABI has refused to postpone the motion to amend the Complaint. However, ABI states that they are "considering settlement possibilities."

DISCUSSION

It is ABI's turn to present their settlement offer as indicated in the letter of May 15, 2001 (Exhibit 2). There does not appear to be any reason why ABI cannot proceed with their settlement proposal within the next 30 days. Issues relating to U.S. Patent No. 4,838,263, owned by the Regents of the University of Minnesota, can be included in the settlement negotiations. An amendment to the Complaint is not necessary to proceed with settlement and will only delay the settlement process. Furthermore, there is no prejudice to ABI or the University in a 30 day moratorium in the motion to amend the Complaint.

REQUESTED ACTION

Electromed requests that the Court proceed as follows:

1. Order the attorneys and persons with authority to settle this litigation to meet within the next 15 days to proceed with settlement negotiations;
2. Order a settlement conference with the Court in the event that the settlement negotiations between the parties do not produce a settlement agreement; and
3. Postpone the motion or decision to amend the Complaint until after the settlement conferences.

Respectfully submitted,

Dated: May 29, 2001

BARTZ & BARTZ, P.A.

By Richard O. Bartz

Richard O. Bartz, #5174
Richard J. Bartz, #166364
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435-1983
Telephone: (952) 920-3959
Facsimile: (952) 920-6494

Attorneys for Defendant
Electromed, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

American Biosystems, Inc.,

Plaintiff,

v.

Civil Action No.

00-2646 DWF/SRN

Electromed, Inc.,

Defendant.

AFFIDAVIT OF R. JOHN BARTZ

R. JOHN BARTZ, being first duly sworn, upon oath, deposes and states as follows:

1. I am an attorney at Bartz & Bartz, P.A., and am one of the attorneys representing Defendant, Electromed, Inc. ("Electromed") with respect to the above matter. Attached to my Affidavit are four (4) Exhibits, each identified hereinbelow.

2. Exhibit 1 is a true and correct copy of correspondence dated May 8, 2001 from Richard O. Bartz to Cyrus A. Morton enclosing a proposed Settlement Agreement.

3. Exhibit 2 is a true and correct copy of correspondence dated May 15, 2001 from Cyrus A. Morton to Richard O. Bartz.

4. Exhibit 3 is a true and correct copy of correspondence dated May 23, 2001 from Richard O. Bartz to Cyrus A. Morton.

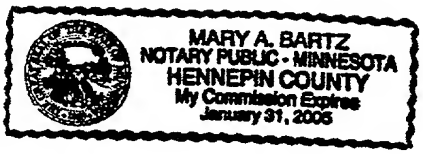
5. Exhibit 4 is a true and correct copy of correspondence dated May 25, 2001 from Cyrus A. Morton to Richard O. Bartz.

FURTHER YOUR AFFIANT SAYETH NOT.

R. John Bartz

Subscribed and sworn to before me

this 29th day of May, 2001.



Notary Public

Law Offices
BARTZ & BARTZ
A Professional Association

Mary A. Bartz
R. John Bartz
Richard O. Bartz

Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435

Tel.: (952) 920-3959
Fax: (952) 920-6494
E-Mail: bartzpa@mcleodusa.net

May 8, 2001

Cyrus A. Morton
Oppenheimer, Wolff & Donnelly, LLP
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402

RE: American Biosystems, Inc. v. Electromed, Inc.
Civil Action 00-2646 DWF/SRN
Your File: 12653113

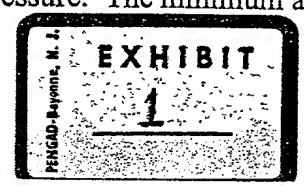
Dear Mr. Morton:

We have reviewed your claim chart concerning the claim of infringement of Claims 1, 2, 4 and 9 of Patent '662 by the Electromed's Medpulse 2000 device. Electromed's claim chart will be prepared in due course.

ABI's basis for contention of infringement is not factually correct. It appears that ABI and its agents do not comprehend the structure and operation of the Medpulse 2000 device. We suggest that the operation of the Medpulse 2000 device be reviewed in detail.

The control for the single DC motor of the Medpulse 2000 device is an OEM component purchased from Minarik Corporation. Enclosed is a copy of the Minarik USER'S MANUAL which includes the specifications for the DC motor speed drive used in Electromed's Medpulse 2000 device. The Minarik control does not have a resistor to measure the voltage drop across the DC motor to control the speed of the motor which determines the frequency at which the two diaphragms are oscillated. There is no feedback voltage from the motor that is compared against a speed setting voltage from the potentiometer. In the Minarik control the voltage applied to the motor is set by the potentiometer controlled with the manual selector knob. Once the potentiometer is set, there are no changes to the voltage to the motor. The motor runs at a constant speed. The Electromed Medpulse 2000 device does not sense the air pressure in the pulse chamber and converts the air pressure to an oscillating electronic signal which is used by a frequency compensating feedback circuit to control the speed of the motor as disclosed and claimed in patent '662.

With regard to the second feedback and control means, the Electromed Medpulse 2000 device does not continuously vary the output pressure of a continuous air flow generator to maintain a peak pressure at a predetermined value. The air pressure in the pulse chamber is not measured and compared against atmospheric pressure. The minimum air pressure in the pulse chamber



never drops below atmospheric pressure. The air pressure in pulse chamber is not compared against a desired peak pressure. The pressure selector is only used to select the air pressure in the vest.

The analysis in the claim chart as to how the air pressure in the Electromed Medpulse 2000 devise and vest is controlled is not correct. ABI does not understand the structure and operation of the Electromed Medpulse 2000 to control the air pressure in the vest.

Enclosed is a proposed settlement agreement for consideration by ABI. We ask that you let us know if ABI will settle this case as set out in the terms of the enclosed settlement agreement.

Very truly yours,

BARTZ & BARTZ, P.A.

Richard O. Bartz

Richard O. Bartz
Attorney at Law

ROB/sja

Encl.

SETTLEMENT AGREEMENT

This agreement is between American Biosystems, Inc. (hereinafter "ABI"), a corporation of Minnesota having a place of business in St. Paul, Minnesota, and Electromed, Inc. (hereinafter "Electromed"), a corporation of Minnesota having a place of business in Minnetonka, Minnesota.

WHEREAS, ABI is the owner of U.S. Patent No. 6,036,662 issued March 14, 2000 titled Oscillatory Chest Compression Device;

WHEREAS, Electromed has designed and manufactured a medical device known as Medpulse 2000 Respiratory Vest System;

WHEREAS, ABI and Electromed are presently adversaries in litigation in the United States District Court of the District of Minnesota, entitled American Biosystems, Inc. v. Electromed, Inc., Civil Action No. 00.2646 DWF/SRN, involving, inter alia, ABI's allegation of patent infringement;

WHEREAS, Electromed has denied ABI's claim in said litigation and has alleged certain affirmative allegations and counterclaim thereto; and

WHEREAS, ABI and Electromed are desirous of settling their differences and disposing of the litigation between them.

NOW THEREFORE, in consideration of the promises and conditions set forth, and other good and valuable considerations, the receipt and sufficiency of which are hereby acknowledged, ABI and Electromed agree as follows:

1. Electromed agrees that it will not make, use, lease and sell a commercial apparatus for generating oscillatory air pulses in a bladder that includes: (1) a first

feedback and control that senses the changes in air pressure in an air pulsing chamber of the apparatus to provide an oscillating electronic signal which is converted to a voltage level proportional to the frequency of the air pressure pulses whereby said voltage is used to adjust the speed of an electric motor used to reciprocate a diaphragm for generating air pressure pulses and maintaining the frequency of the air pressure pulses at a predetermined level, and (2) a second feedback and control that senses the air pressure in an air pulsing chamber of the apparatus to provide an electric signal which is converted to a voltage level proportional to the air pressure in the air pulsing chamber whereby said voltage is used to continuously vary the output pressure of a continuous air flow generator in order to maintain the peak air pressure in the pulsing chamber at a predetermined volume during the term of patent '662 or until patent '662 is abandoned, or held invalid by a U.S. court.

2. ABI agrees that Electromed can make, use, lease, and sell the Electromed Medpulse 2000 Respitatory Vest System.

3. ABI and Electromed release each other, and their respective directors, officers, agents, employees, servants, representatives, suppliers, and customers, and each and all of them, from any and all liability for damages, profits, or attorney's fees through the date of this agreement arising from any acts alleged in the aforesaid litigation.

4. ABT and Electromed shall cause their counsel to execute and submit to the Court a Stipulation of Dismissal with Prejudice in the aforesaid litigation.

5. This agreement shall be binding upon ABI and Electromed and their respective successors and assigns, and it may be specifically enforced by a civil action subject to the provisions of paragraph 6 below.

6. This agreement may be enforced in a civil action by either party upon a material breach of any of the promises or conditions recited herein, and ABI and Electromed both irrevocably agree that any such civil action may be brought in the United States Courts located in the State of Minnesota, and they hereby consent to the jurisdiction of such Courts and waive any objections that they may have to venue in such Courts.

7. ABI and Electromed each respectively acknowledges that it enters into this agreement as its own free act and deed, based upon its own judgment, beliefs, and knowledge as to all phases of the aforesaid litigation, and based upon the advice of its own counsel.

8. **IN WITNESS WHEREOF**, ABI and Electromed execute this agreement, to be effective as of the last date set forth below.

American Biosystems, Inc.

Date_____ By_____

Electromed, Inc.

Date_____ By_____
Robert D. Hansen, President

OPPENHEIMER

OPPENHEIMER WOLFF & DONNELLY LLP

Brussels
Geneva
Los Angeles
Minneapolis
New York
Orange County
Paris
Silicon Valley
Washington, D.C
oppenheimer.co

Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402-1609

612.607.7000
Fax 612.607.7100

Direct Dial: *612.607.7354*
E-Mail: *C Morton@oppenheimer.com*

May 15, 2001

Richard O. Bartz, Esq.
Bartz & Bartz
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435

Re: American Biosystems, Inc. v. Electromed, Inc.
Court File Number: 00-2646 DWF/SRN
Our File No.: 12653/13

Dear Mr. Bartz:

In response to your letter of May 8, 2001, I thank you for your additional document production including the User's Manual for the Minarik motor. However, I would appreciate it if you would endeavor to perform a complete document production rather than a piece meal production of documents that you would like to discuss at that particular point in the litigation. With regard to your arguments on the merits of the MedPulse 2000, I refer you to your Bates No. 000133 discussing IR COMP, which clearly contemplates feedback. Moreover, Electromed will certainly have an opportunity to make its argument on this matter in its claim chart.

I have reviewed your settlement proposal with my client. The proposal amounts to an admission by ABI that the MedPulse 2000 does not infringe the '662 Patent, an admission that my client is not inclined to make. We are however, interested in continuing settlement discussions and are in the process of preparing our own settlement offer which we will make in due course.

Sincerely,

Cyrus A. Morton

CAM:slo

Law Offices
BARTZ & BARTZ
A Professional Association

Mary A. Bartz
R. John Bartz
Richard O. Bartz

Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, Minnesota 55435

Tel.: (952) 920-3959
Fax: (952) 920-6494
E-Mail: bartzpa@mcleodusa.net

May 23, 2001

Cyrus A. Morton, Esq.
Oppenheimer, Wolff & Donnelly, L.L.P.
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402-1609

Re: American Biosystems, Inc. v. Electromed, Inc.
Civil Action No.: 00-2646 DWF/SRN

Dear Mr. Morton:

We note from you letter of May 15, 2001 that American Biosystems, Inc. has not accepted nor rejected the enclosed Settlement Agreement proposed by Electromed, Inc.

You state that "[w]e are however, interested in continuing settlement discussions and are in the process of preparing our own settlement offer which we will make in due course."

We suggest that ABI expedite its proposed settlement so the litigation can be concluded without further adversary proceedings. Electromed has always been willing to proceed with settlement discussions with ABI.

We suggest that the Motion to Amend the Complaint be postponed for 30 days and that settlement discussions proceed in the next 30 days.

Very truly yours,

BARTZ & BARTZ, P.A.

Richard O. Bartz

Richard O. Bartz

ROB/gn

Encl.

OPPENHEIMER

OPPENHEIMER WOLFF & DONNELLY LLP

Brussels
Geneva
Los Angeles
Minneapolis
New York
Orange Count
Paris
Silicon Valley
Washington, I
oppenheimer.c

Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402-1609

612.607.7000
Fax 612.607.7100

Direct Dial: 612.607.7354
E-Mail: C Morton@oppenheimer.com

May 25, 2001

VIA FACSIMILE
AND U.S. MAIL

Richard O. Bartz, Esq.
Bartz & Bartz
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435

Re: American Biosystems, Inc. v. Electromed, Inc.
Court File Number: 00-2646 DWF/SRN
Our File No.: 12653/13

Dear Mr. Bartz:

I have received your letter of May 23, 2001 wherein you indicate your desire to postpone the motion to amend the complaint for 30 days in order to discuss settlement. We have not agreed and will not agree to postpone the motion. We have repeatedly entertained through correspondence your baseless opposition to the amendment and refusal to sign a stipulation for the amendment. This matter has been drawn out long enough. Moreover, the motion now stands unopposed as you have failed to serve responsive papers 7 days prior to the hearing date as required by Local Rule 7.1.

As for your suggestion that American Biosystems, Inc. has not accepted nor rejected Electromed's latest settlement agreement, I disagree. When I stated in my May 15, 2001 letter that Electromed's offer "amounts to an admission by ABI that the MedPulse 2000 does not infringe the '662 Patent, an admission that my client is not inclined to make," I meant that my client would not accept your offer and that your offer was rejected. I will try to use plainer language in the future.

I do stand by my earlier statement that ABI is considering settlement possibilities. However, your offer that ABI essentially dismiss its case and give up its intellectual property rights *vis-à-vis* the MedPulse 2000 is a non-starter. It is not at all the kind of offer that would warrant postponing any aspect of this litigation for the purpose of discussing settlement. Additionally, my client intends to

OPPENHEIMER

OPPENHEIMER WOLFF & DONNELLY LLP

enforce its rights under the '263 patent as clearly evidenced by the pending motion to amend. Thus, your attempt to postpone the motion under the guise of a settlement proposal without any reference to the '263 patent can be seen for what it is, a delay tactic, not a bona fide settlement offer. Accordingly, the offer is again rejected and the motion to amend is not postponed.

Sincerely,

Cyrus A. Morton

CAM:slo

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

American Biosystems, Inc.,

Plaintiff,

Civil Action No.

v.

00-2646 DWF/SRN

Electromed, Inc.,

Defendant.

PROPOSED ORDER

The above-entitled matter came on for hearing before the Honorable Susan R. Nelson, Magistrate Judge of District Court, on the ____ day of ____________, 2001, in Chambers at 242 U.S. Courthouse, 316 North Robert Street, St. Paul, Minnesota.

The matter was before the Court upon the Motion of Defendant for settlement conference and postponement of Plaintiff's motion to amend the Complaint.

The Court, having heard the arguments of counsel, and upon all the files, records and proceedings herein, and being fully advised of the premises, makes the following Order:

1. The attorneys and persons with authority to settle this litigation shall meet within the fifteen (15) days from the date of this Order for settlement negotiations;
2. The parties shall advise the Court in the event that the settlement negotiations did not result in a settlement agreement and arrange for settlement conference with the Court; and
3. The motion to amend the Complaint is postponed until after the settlement conference.

SO ORDERED BY THE COURT:

Dated:____________________

____
Magistrate Judge Susan R. Nelson

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

AMERICAN BIOSYSTEMS, INC.,

Plaintiff,

v.

ELECTROMED, INC.,

Defendant.

Civil No. 00-2646 (DWF/SRN)

ORDER

Edward M. Laine, Esq., and Cyrus A. Morton, on behalf of Plaintiff American Biosystems, Inc.

Richard O. Bartz, Esq., on behalf of Defendant Electromed, Inc.

SUSAN RICHARD NELSON, United States Magistrate Judge

The above-entitled matter came on for hearing before the undersigned Magistrate Judge of District Court on May 31, 2001, on motions of both parties. Plaintiff American Biosystems, Inc. (ABI) moved, pursuant to Fed. R. Civ. P. 15(a), for leave to file an amended Complaint in the form set forth in the proposed Amended Complaint attached to ABI's Notice of Motion and Motion to Amend Complaint. Defendant Electromed, Inc. moved, pursuant to Fed. R. Civ. P. 16(a), for an order directing the attorneys for the parties and

persons with authority to settle this litigation to: 1) meet within the next fifteen days for settlement negotiations; 2) appear before the Court for a conference for the purpose of facilitating the settlement of the case; and 3) postpone the motion to amend the Complaint or postpone the decision on such motion until after the settlement conference.

A. ABI's Motion for Leave to Amend the Complaint

ABI seeks leave to amend its Complaint to add a count for infringement of U.S. Patent No. 4,838, 263 (the '263 patent) against Defendant Electromed. The proposed Amended Complaint is attached to ABI's Notice of Motion and Motion to Amend Complaint, as is the '263 Patent. ABI submits that subsequent to the filing of this lawsuit, it discovered that the '263 Patent was being infringed by Electromed. ABI unsuccessfully sought a stipulation to amend the Complaint from Electromed, and this motion resulted.

During oral argument on the motions, counsel informed the Court that settlement discussions were under way in this matter. Hence, the Court informed counsel that a formal ruling on the Plaintiff's motion for leave to amend the Complaint would be held in abeyance until June 11, 2001, when the parties were to report their progress to the Court. Otherwise, in the absence of a settlement, the Court advised the parties that the Plaintiff's motion would be granted.

In letters dated June 11th, the parties informed the Court that no

settlement discussions had taken place in the first week of June. Accordingly, the Court grants Plaintiff ABI's motion for leave to amend the Complaint to add a count for infringement of U.S. Patent No. 4,838,263 against Electromed. The motion is timely under the terms of the Pretrial Scheduling Order.

Federal Rule of Civil Procedure 15(a) provides that a court may allow amendments to pleadings "when justice so requires." In interpreting this rule the Supreme Court has stated:

> If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded the opportunity to test his claims on the merits. In the absence of any apparent or declared reason -- such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment
> . . ., the leave sought should, as the rules require, be "freely given."

Foman v. Davis, 371 U.S. 178, 182 (1962). Neither delay nor dilatory motive are sufficient in themselves to deny a party leave to amend a pleading. The delay or dilatory motive must result in prejudice to the party opposing the motion. Buder v. Merrill Lynch, Pierce, Fenner & Smith, 644 F.2d 690, 694 (8th Cir. 1981). Even if some prejudice would result to the adverse party if the motion to amend were granted, that prejudice must be balanced against the hardship to the moving party if it is denied. Id.

The Eighth Circuit has found that leave to amend may be properly

denied when the proposed amendment would be futile. See Holloway v. Dobbs, 715 F.2d 390, 393-94 (8th Cir. 1983). The Eighth Circuit has also held, however, that amendments should be denied on the merits of the claim only if the amendment asserts clearly frivolous claims. Buder v. Merrill Lynch, Pierce, Fenner & Smith, 644 F. 2d at 694. The determination as to whether to grant leave to amend is entrusted to the sound discretion of the trial court. Niagra of Wisconsin Paper Corp. v. Paper Industry Union Management Pension Fund, 800 F.2d 742, 749 (8th Cir. 1986).

In light of the liberal standards governing motions seeking leave to amend under Fed. R. Civ. P. 15(a), this Court grants Plaintiff ABI's motion. In its proposed Amended Complaint, ABI alleges it is the exclusive licensee of the '263 Patent and, accordingly, possesses the right to sue on the patent. See ¶ 9 of the Amended Complaint. The Court finds that ABI ought to be given an opportunity to test, on the merits, its claim that Electromed has infringed ABI's '263 Patent. In addition, the Court finds no undue delay, no bad faith or dilatory motive, nor has there been a repeated failure to cure by amendment, as this is the first request for leave to amend the Complaint. Furthermore, the Court finds that the amendment is not clearly futile, and judicial economy dictates that the amendment should be allowed. As such, Plaintiff American Biosystems, Inc. is granted leave to file and serve its Amended Complaint in the form attached to its Notice of Motion and Motion to Amend Complaint.

B. Electromed's Motions for Settlement Conference and Postponement of Motion to Amend Complaint

Defendant Electromed moved pursuant to Fed. R. Civ. P. 16(a), for an order directing the attorneys for the parties and persons with authority to settle this litigation to: 1) meet within the next fifteen days for settlement negotiations; 2) appear before the Court for a conference for the purpose of facilitating the settlement of the case; and 3) postpone the motion to amend the Complaint or postpone the decision on such motion until after the settlement conference.

At the hearing on these motions, the Court expressed its willingness to schedule a formal settlement conference in this case. However, the Defendant's motion to compel attendance at such a conference is denied at this time. If there is no mutual desire to discuss settlement at this juncture in the case, then such an undertaking would be fruitless.

The issue will be discussed during the status conference which the Court requests the parties to schedule in order to address any expansion of the Pretrial Scheduling Order necessitated by the amendment of the Complaint to add the '263 Patent infringement claims. The Court directs that the parties meet prior to the status conference to re-work the schedule for presentation to the Court.

Electromed's motion for postponement of ABI's motion to amend the Complaint is denied.

Based on the foregoing, and all the files, records and proceedings herein,

IT IS HEREBY ORDERED that:

1) Plaintiff American Biosystems, Inc.'s Motion for Leave to Amend the Complaint to add a count for infringement of U.S. Patent No. 4,838, 263 (Doc. No. 8) is **GRANTED**. Plaintiff shall, within ten days of the date of this Order, file and serve its Amended Complaint in the form attached to its Notice of Motion and Motion. Defendant Electromed, Inc. shall serve an Amended Answer thereto within twenty days after being served;

2) Defendant Electromed, Inc.'s Motion for Settlement Conference (Doc. No. 12) is **DENIED WITHOUT PREJUDICE**. The parties shall schedule a status conference with this Court for purposes of discussing, inter alia, any changes in the Pretrial Scheduling Order necessitated by the amendment to the Complaint, and shall meet prior to the status conference to re-work the schedule for presentation to the Court;

3) Defendant Electromed, Inc.'s Motion for Postponement of the Motion to Amend Complaint (Doc. No. 12) is **DENIED**.

Dated: June 21, 2001.

SUSAN RICHARD NELSON
United States Magistrate Judge

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	Case Number: 00-2646 DWF/SRN **AMENDED COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

Plaintiff American Biosystems, Inc. ("American Biosystems"), for its Complaint for Patent Infringement against Defendant Electromed, Inc. ("Electromed") states and alleges as follows:

PRELIMINARY STATEMENT

1. This is an action by American Biosystems to enforce United States Patents numbered 6,036,662 (the '662 Patent) and 4,838,263 (the '263) which are being infringed by Electromed. American Biosystems is a Minnesota corporation that manufactures and distributes innovative oscillatory chest compression devices throughout the United States. These devices represent a major advancement in the treatment of numerous respiratory disorders, and specifically, cystic fibrosis. American Biosystems owns and licenses patents covering this technology which generally relates to a device including a vest with a bladder that is inflated with air to suitable pressure. A diaphragm is then used to oscillate the pressure in the vest causing pulses or blows to the chest cavity thereby loosening, and assisting in the expulsion of, secretions in a person`s lungs.

2. Electromed also manufacturers and distributes chest compression devices throughout the United States. American Biosystems' sales of its devices compete directly with

Electromed's sales. Although Electromed has no license or other right to use American Biosystem's patented technology, Electromed has introduced a device utilizing the same type of oscillatory pressure system that is the subject of the '662 and '263 Patents. As alleged in more detail in this complaint, Electromed's product infringes American Biosystems patents.

PARTIES, JURISDICTION AND VENUE

3. American Biosystems is a corporation organized and existing under the laws of Minnesota with its principal place of business in St. Paul, Minnesota.

4. Electromed is a corporation organized and existing under the laws of Minnesota with its principal place of business in Minnetonka, Minnesota.

5. This is a claim of patent infringement arising under 35 U.S.C. §§ 271 and 281, 283-85.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

7. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1400(b) because Electromed resides in this district, because a substantial part of the conduct giving rise to American Biosystems' claims occurred in this district, and because Electromed has committed acts of infringement in this district.

GENERAL ALLEGATIONS

A. The Patents In Issue.

8. On March 14, 2000, the United States Patent and Trademark Office duly and legally issued United States Patent No. 6,036,662, which claims an apparatus for generating

oscillatory air pulses in a bladder positioned about a person. The '662 Patent issued to American Biosystems as assignee of the inventors Nicholas P. Van Brunt and Donald J. Gagne. A true and correct copy of the '662 Patent is attached hereto as Exhibit A. American Biosystems is the owner of the entire right, title and interest in and to the '662 Patent.

9. On June 13, 1989, the United States Patent and Trademark Office duly and legally issued United States Patent No. 4,838,263, which claims an oscillatory chest compression apparatus for a person. The '263 Patent issued to Regents of the University of Minnesota as assignee of the inventors Warren J. Warwick and Leland G. Hansen. A true and correct copy of the '263 Patent is attached hereto as Exhibit B. By virtue of an agreement with the University of Minnesota dated November 2, 1988, American Biosystems is the exclusive licensee of '263 Patent and has the explicit right to sue alleged infringers of the '263 Patent.

B. Electromed's Infringing Product.

10. Electromed is the manufacturer of the Medpulse™ Respiratory Vest system. The system includes an inflatable vest and a portable air pulse generator which provides oscillatory air pressure for loosening and assisting in the expulsion of secretions in a person's lungs.

C. Claim for Infringement of the '662 Patent.

11. American Biosystems incorporates the allegations contained in Paragraphs 1 through 10 as though restated herein in their entirety.

12. Electromed has engaged in activities directed toward the imminent making, selling or using of a chest compression device with oscillatory air pressure and feedback system controls for controlling the pressure exerted on the body.

13. Electromed is directly infringing claims of the '662 Patent by making, offering to sell and selling chest compression devices with oscillatory air pressure and feedback system controls for controlling the pressure exerted on the body.

14. Electromed is actively inducing infringement of claims of the '662 Patent by others, in that Electromed is intentionally aiding and abetting others to infringe claims of the patent, including by offering products which have no substantial non-infringing use or purpose. On information and belief, Electromed's devices have been used by others and such use is direct infringement.

15. American Biosystems has been damaged by Electromed's infringement of the American Biosystems' patent and will continue to be damaged and irreparably harmed in the future unless Electromed is enjoined from infringing the patents.

16. On information and belief, Electromed has infringed the American Biosystems' patent willfully at all times. Electromed will have had actual knowledge of the '662 Patent at least since the time of service of this complaint and its continuing infringement is willful and deliberate.

D. Claim for Infringement of the '263 Patent.

17. American Biosystems incorporates the allegations contained in Paragraphs 1 through 16 as though restated herein in their entirety.

18. Electromed has engaged in activities directed toward the imminent making, selling or using of oscillatory chest compression devices with a means for controlling the pressure exerted on the body.

19. Electromed is directly infringing claims of the '263 Patent by making, offering to sell and selling chest compression devices with oscillatory air pressure pulses exerted on the body.

20. Electromed is actively inducing infringement of claims of the '263 Patent by others, in that Electromed is intentionally aiding and abetting others to infringe claims of the patent, including by offering products which have no substantial non-infringing use or purpose. On information and belief, Electromed's devices have been used by others and such use is direct infringement.

21. American Biosystems has been damaged by Electromed's infringement of the '263 Patent and will continue to be damaged and irreparably harmed in the future unless Electromed is enjoined from infringing the patents.

22. On information and belief, Electromed has infringed the '263 Patent willfully at all times. Electromed will have had actual knowledge of the '263 Patent at least since the time of service of this complaint and its continuing infringement is willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, American Biosystems prays for the following relief:

1. A declaration that Electromed's Medpulse Respiratory Vest System infringes United States Patent Nos. 6,036,662 and 4,838,263;

2. Preliminary and permanent injunctions enjoining and restraining Electromed, its officers, directors, agents, servants, employees and all others acting under or through it, directly or indirectly, from infringing United States Patent Nos. 6,036,662 and 4,838,263.

3. A judgment requiring Electromed to pay damages under 35 U.S.C. § 284, including a judgment that infringement has been willful, along with trebling of damages, with interest;

4. A judgment requiring Electromed to pay the costs and disbursements of this action and attorney's fees as provided by 35 U.S.C. § 285, with interest; and

5. Such other and further relief as the Court may deem just and equitable.

Date: June 22, 2001

OPPENHEIMER WOLFF & DONNELLY LLP

By _____

Edward M. Laine, #59535
Cyrus A. Morton, #287325
David J. McKinley, #295814
3300 Plaza VII Building
45 South 7th Street
Minneapolis, MN 55402
Phone: (612) 607-7000
Fax No.: (612) 607-7100

ATTORNEYS FOR PLAINTIFF

US006036662A

United States Patent [19]

Van Brunt et al.

[11] Patent Number: 6,036,662

[45] Date of Patent: *Mar. 14, 2000

[54] OSCILLATORY CHEST COMPRESSION DEVICE

[75] Inventors: Nicholas P. Van Brunt, White Bear Lake; Donald J. Gagne, St. Paul, both of Minn.

[73] Assignee: American Biosystems, Inc., St. Paul, Minn.

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: 09/039,606

[22] Filed: Mar. 16, 1998

Related U.S. Application Data

[63] Continuation of application No. 08/661,931, Jun. 11, 1996, Pat. No. 5,769,797.

[51] Int. Cl.[7] A61H 31/00

[52] U.S. Cl. 601/41; 601/44; 601/152

[58] Field of Search 601/41–44, 48, 601/55, 56, 77, 148–152; 128/DIG. 20; 602/13

[56] References Cited

U.S. PATENT DOCUMENTS

3,063,444	11/1962	Jobst .	
3,536,063	10/1970	Werding .	
3,896,794	7/1975	McGrath .	
3,993,053	11/1976	Grossan .	
4,133,305	1/1979	Steuer .	
4,186,732	2/1980	Christoffel	601/150
4,815,452	3/1989	Hayek .	
4,838,263	6/1989	Warwick et al. .	
4,977,889	12/1990	Budd .	
5,056,505	10/1991	Warwick et al. .	
5,188,097	2/1993	Hansen	601/134
5,453,081	9/1995	Hansen .	
5,606,754	3/1997	Hand et al. .	

FOREIGN PATENT DOCUMENTS

0542383A2	5/1993	European Pat. Off. .

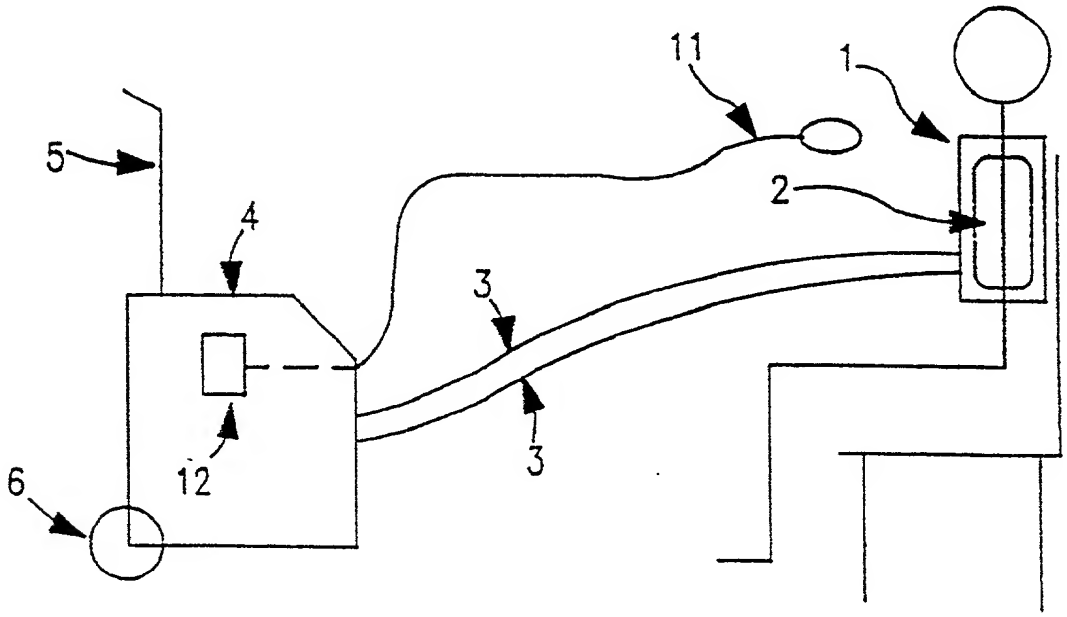
Primary Examiner—Danton D. DeMille

Attorney, Agent, or Firm—David B. Edgeworth

[57] ABSTRACT

An oscillatory chest compression device includes an oscillatory air flow generator and a positive air flow generator. A first feedback system controls the oscillation rate of the oscillatory air flow generator, and a second feedback system controls the peak pressure created by the positive air flow generator.

12 Claims, 3 Drawing Sheets



EX. A

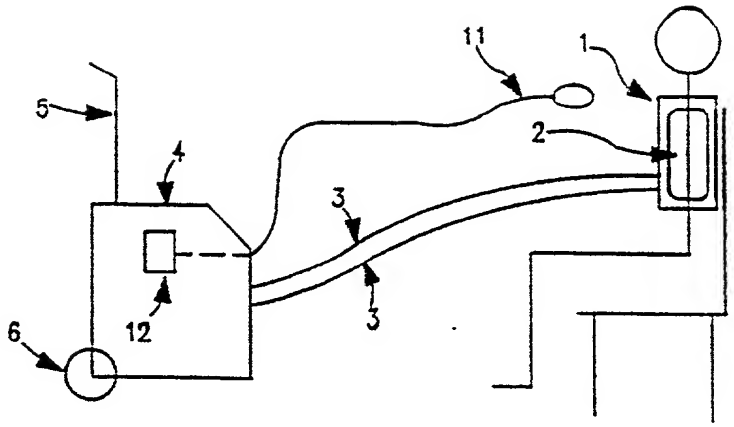


FIG. 1

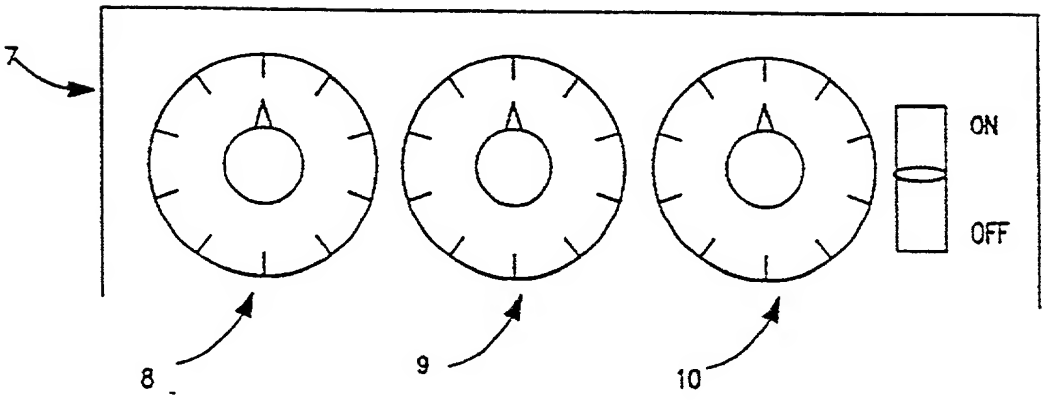


FIG. 2

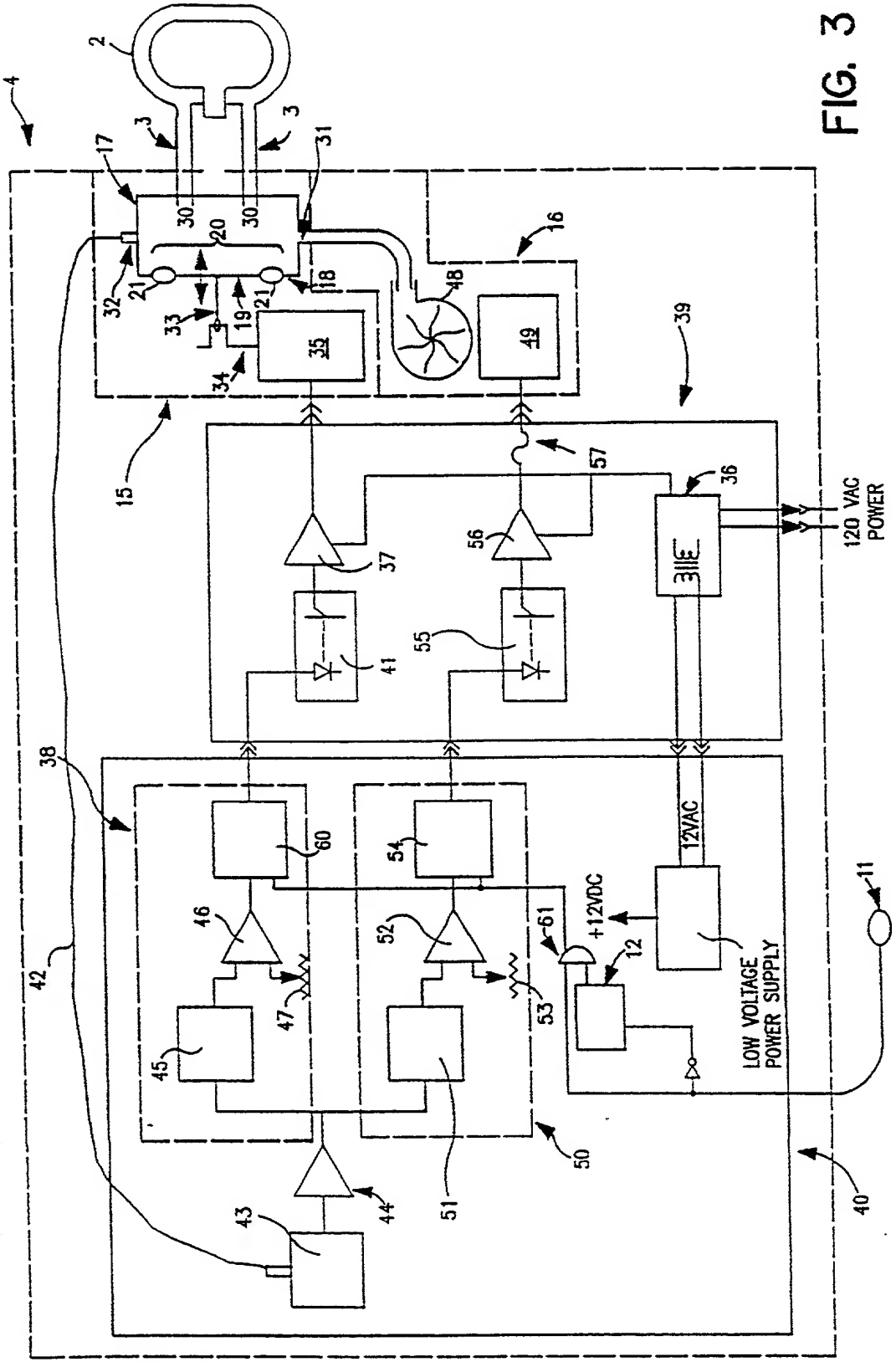


FIG. 3

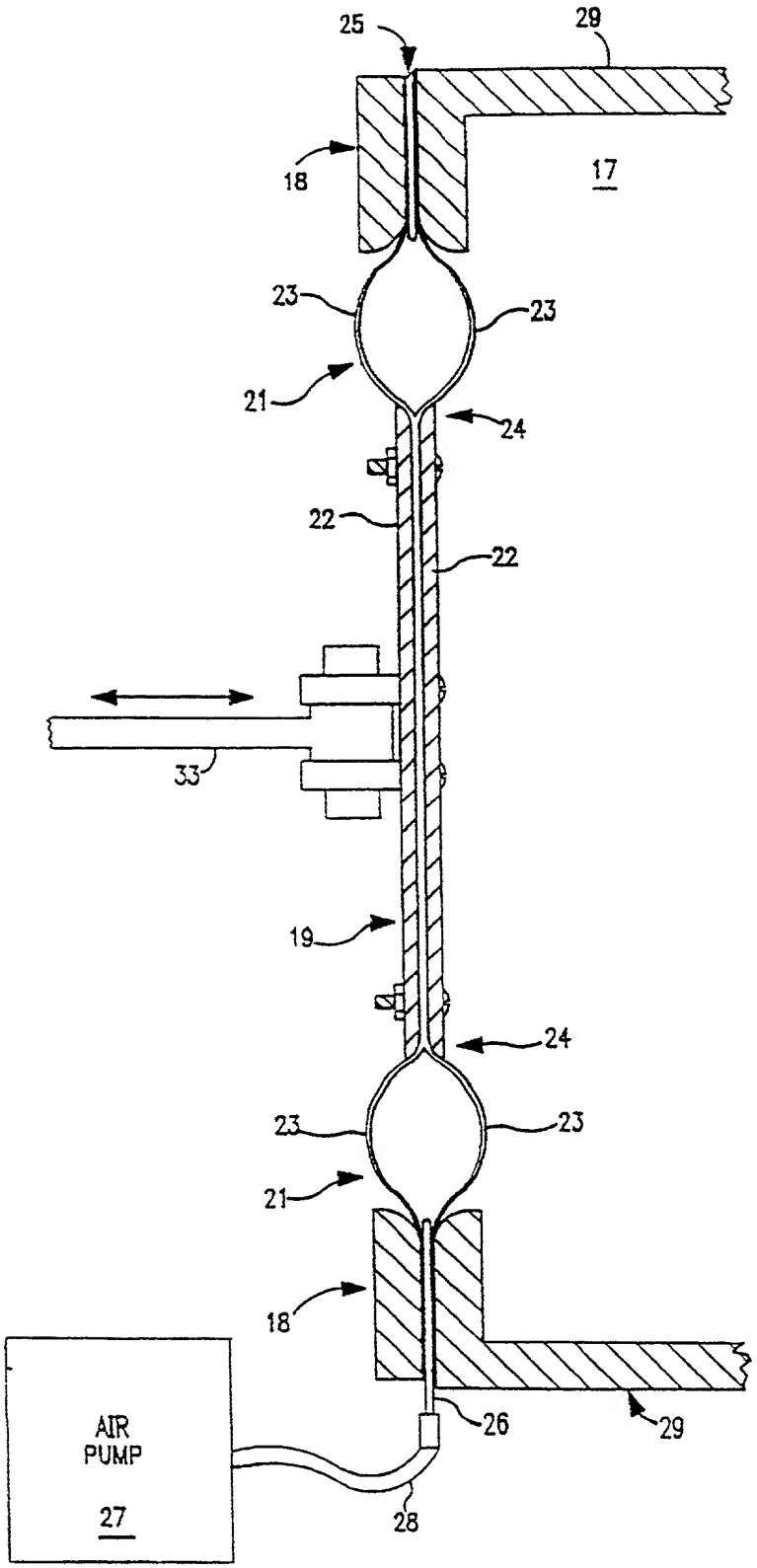


FIG. 4

OSCILLATORY CHEST COMPRESSION DEVICE

This is a continuation of application Ser. No. 08/661,931, filed Jun. 11, 1996, now U.S. Pat. No. 5,769,797.

FIELD OF THE INVENTION

The present invention relates to an oscillatory chest compression device.

BACKGROUND OF THE INVENTION

Certain respiratory disorders, such as cystic fibrosis, emphysema, asthma, and chronic bronchitis, may cause mucous and other secretions to build up in a person's lungs. It is desirable, and sometimes essential, that the secretion build-up be substantially removed from the lungs to enable improved breathing. For example, Cystic fibrosis is an hereditary disease that affects the mucous secreting glands of a person, causing an excessive production of mucous. The mucous fills in the person's lungs and must be reduced daily to prevent infection and enable respiration by the person.

Currently there is no cure for cystic fibrosis. Current treatment of cystic fibrosis includes an aerosol therapy to assist lung drainage and repeated pounding on the upper torso of the person to loosen and expel the mucous. This daily treatment may take several hours and requires a trained individual to apply the pounding treatment.

Pneumatic and mechanical systems have been developed for loosening and removing secretions from a person's lungs. In one pneumatic system, a bladder is positioned around the upper torso of the patient. One or more hoses connect the bladder with a mechanism for generating air pulses in the bladder. The pulsing of the bladder provides chest compressions to the patient. The pulsing frequency is independent of and higher than the patient's breathing rate. One such system, disclosed in U.S. Pat. No. 4,838,263, is a valve-operated, open-loop system that requires the patient to interact with the system throughout the treatment period.

Other systems include mechanical vibrators. Some vibrator systems are attached to the person's torso, while others are hand-held. Vibrators and other direct mechanical compression devices are likely to be heavier than pneumatic compression devices.

A chest compression device, as is the case with medical devices generally, must meet a variety of requirements. First, the chest compression device must be safe to operate. The patient receiving treatment should not be able to adjust the device to create unsafe treatment conditions. Failure of device components must not create unsafe conditions. The chest compression device should provide some user control, allowing the device to be customized to the needs of individual users. The device should be easy to understand and operate by the user; detailed training and complicated controls increase the cost of the treatment. Finally, the device should minimize intrusion into the daily activities of the user.

SUMMARY OF THE INVENTION

The present invention is directed to an oscillatory chest compression device that loosens and assists in expulsion of secretions in a person's lungs. A vest, containing a bladder, is secured to a patient's upper torso. One or more tubes connect the bladder with a generator. The generator includes a first, oscillatory air flow generator. A second, positive air flow generator is operably connected with the oscillatory air flow generator. Feedback systems control both the oscillatory air flow generator and the positive air flow generator, providing treatment at user-selected parameters and preventing unsafe conditions.

The inventors of the present invention were the first to recognize several design aspects that result in an efficacious, safe, and easy-to-use oscillatory chest compression device. The oscillatory air flow generator includes a reciprocating diaphragm. The reciprocating diaphragm delivers a generally constant pressure throughout the range of oscillation frequencies, providing efficacious treatment throughout the range of user-selectable frequency settings. The reciprocating diaphragm provides a more efficient transfer of electrical energy to pneumatic energy as compared to prior rotary-valve designs.

One major safety concern in a pneumatic chest compression device is over-pressurization of the bladder. The reciprocating diaphragm provides inherently safe pressure conditions. The only way a reciprocating diaphragm can increase pressure in the bladder is to increase the diaphragm stroke length or diameter. However, there is no failure mode that will increase the stroke length or diameter of the reciprocating diaphragm.

The present invention includes a positive air flow generator operably connected with the oscillatory air flow generator. The positive air flow generator compensates for any leakage in the system, including the hoses and bladder. Also, the positive air flow generator, in connection with a feedback system, maintains the desired peak pressure delivered by the bladder, independent of variations in the bladder and the patient. The positive air flow generator includes the safety feature of a fuse connected with the input power. The fuse is rated so as to prevent a power surge from causing the positive air flow generator to generate an unsafe, high pressure.

The oscillatory chest compression device of the present invention is automated, allowing the user to select operating parameters for a treatment and then direct his attention to other matters. The feedback systems of the present invention maintain the user-selected parameters during the treatment. The user controls are selected so that the user cannot select operating parameters that would result in unsafe chest compression treatment.

Other advantages and features will become apparent from the following description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects of the present invention will be described in detail with respect to the accompanying drawings, in which:

FIG. 1 is an illustration of a person and a chest compression device;

FIG. 2 is a schematic diagram of the control panel of a chest compression device;

FIG. 3 is a schematic diagram of a chest compression device; and

FIG. 4 is a schematic diagram of a portion of a chest compression device.

DETAILED DESCRIPTION OF THE EMBODIMENTS

A chest compression device is shown in FIG. 1. A vest 1 is secured about the torso of a patient. A bladder 2 is fitted within vest 1. Oscillatory air pulses are delivered to bladder 2. The outer surface of vest 1 is made of a non-stretch

material, causing the expansions and contractions of bladder 2 to occur generally adjacent the patient's torso. The expansions and contractions create a pneumatic, oscillatory compression of the patient's torso to loosen and assist the expulsion of mucous and other secretions in the patient's lungs. Suitable vests are available from American Biosystems, Inc., St. Paul, Minn., the assignee of the present invention.

Tubes 3 connect bladder 2 with generator 4. Two tubes 3 are shown in FIGS. 1 and 3; however, the number of tubes 3 may be varied depending on the desired operating parameters of bladder 2. Generator 4 generates oscillatory air pulses in accordance with user-selected settings. The pulses are converted into compressions of the patient's torso by bladder 2. Generator 4 may be configured as a mobile unit with handle 5 and wheels 6, or as a stationary unit.

Generator 4 includes a control panel 7, shown in FIG. 2. Timer 8 allows the user to select a treatment period. Frequency selector 9 allows the user to select the frequency of compressions. In one embodiment, the frequency range is about five to twenty-five Hz. Pressure selector 10 allows the user to select the peak pressure for each oscillation. In one embodiment, the pressure range is about 0.2 to 0.6 PSI.

As shown in FIG. 1, the user typically is seated during treatment. However, the user has some local mobility about generator 4, determined by the length of hoses 3. Also, the mobile unit shown in FIG. 1 may be easily transferred to different locations. For treatment, the user selects the desired operating parameters and no further interaction by the user is required; generator 4 maintains the user-selected parameters. The user may change the settings at any time. A remotely-operated control 11 allows the user to start and stop the treatment.

Generator 4 also includes a ten-minute safety timer 12. Once the user initiates treatment, safety timer 12 starts. Safety timer 12 is reset each time the user activates start/stop control 11. If the safety timer expires, generator 4 is turned off. Therefore, even if the user loses consciousness or is otherwise incapacitated, generator 4 is turned off after a predetermined period, reducing the likelihood of injury to the user due to an excessive period of chest compressions.

A block diagram of generator 4 is shown in FIG. 3. Generator 4 includes two air flow units, oscillatory air flow generator 15 and positive air flow generator 16. Oscillatory air pulses are generated by oscillatory air flow generator 15. Oscillatory air flow generator 15 includes an air chamber 17. Air chamber 17 includes a wall 18 having a reciprocating diaphragm 19 suspended in an aperture 20 of wall 18 by a seal 21.

As shown in FIG. 4, diaphragm 19 is a generally rigid disk assembly of two opposed, generally circular disks 22. Flexible, air-tight seal 21 is formed by two rubber disks 23 positioned between diaphragm disks 22. Diaphragm disks 22 are clamped together by bolts or other fastening means. Rubber disks 23 extend from the outer periphery 24 of diaphragm disks 22 into a groove 25 in wall 18, thereby forming a generally air-tight seal in the gap between diaphragm 19 and wall 18.

Air pressure is supplied to seal 21 by capillary tube 26, which is supplied by air pump 27 and tubing 28. Air pump 27 maintains the air pressure in seal 21 higher than the maximum pressure peaks in air chamber 17. In one embodiment, the air pressure in seal 21 is maintained at about 1.5 PSI. The pressure relationship causes rubber disks 23 to maintain the inflated shape as shown in FIG. 4 as diaphragm 19 reciprocates. This results in a smooth, quiet, low-friction travel of diaphragm 19, while maintaining an airtight seal between diaphragm 19 and wall 18.

The remaining walls 29 of air chamber 17 are generally rigid. Apertures 30 provide fluid communication between air chamber 17 and tubes 3. Aperture 31 provides fluid communication with positive air flow generator 16. Aperture 32 provides fluid communication with the control system described below.

Diaphragm 19 is mechanically connected through rod 33 to a crankshaft 34, which is driven by motor 35. Each rotation of crankshaft 34 causes a fixed volume of air (defined by the area of the diaphragm multiplied by the length of the stroke) to be displaced in air chamber 17. The pressure changes inside air chamber 17 resulting from the displacements are relatively small (e.g., less than one PSI) in comparison to the ambient air pressure. Therefore, there is little compression of the air in air chamber 17 and the majority of the displaced air is moved into and out of bladder 2 through tubes 3 during each cycle. This results in the amount of air transferred into and out of bladder 2 during each cycle being largely independent of other factors, such as the oscillation frequency and bladder size.

In one embodiment, motor 35 is a permanent magnet DC brush motor. The motor speed is generally controlled by the voltage supplied to it. A 170 volt DC power supply 36 energizes power amplifier 37. Power amplifier 37 is controlled by a frequency-compensation feedback circuit 38, thereby supplying variable length pulses to motor 35. The inductance of motor 35 effectively smoothes the pulses to a constant power level that is proportional to the ratio of the pulse length divided by the pulse period. Using a pulse period of 20 kHz, the pulse length controls the motor speed.

As shown in FIG. 3, all of the power circuitry is located on power board 39. The control circuitry is located on a separate, low-energy control board 40. The control board 40 is connected to the power board 39 by 5000-volt opto-isolators 41, 55. The high level of isolation between the power board 39 and control board 40 provides significant shock protection for the user.

Conduit 42 conveys changes in pressure from air chamber 17 to pressure transducer 43. Pressure transducer 43 converts the air pressure into an oscillating electronic signal, which is then amplified by amplifier 44. The output of amplifier 44 is then processed by frequency-compensation feedback circuit 38.

Frequency-to-voltage converter 45 converts the oscillating signal to a voltage level proportional to the frequency. The output of converter 45 is fed to difference amplifier 46. Difference amplifier 46 has a second input 47 representing the user-selected frequency setting. Difference amplifier 46 compares the voltage representing the user-selected frequency with the voltage representing the actual frequency detected in air chamber 17. The output of difference amplifier 46 is input into pulse-width modulator 60. The output of pulse-width modulator 60 is fed through opto-isolator 41 and power amplifier 37 to motor 35, thereby adjusting the speed of motor 35 and, consequently, the oscillation frequency in air chamber 17.

Reciprocating diaphragm 19 of oscillatory air flow generator 15 provides several advantages. First, the amount of air transferred into and out of bladder 2 during each cycle is largely independent of the oscillation frequency setting. In prior art systems, using a constant air flow and valve configuration, less air flow was delivered at higher frequencies. Therefore, the present invention provides a more consistent air flow over the user selectable frequency range. This consistency provides a more efficacious treatment.

Further, reciprocating diaphragm 19 is both efficient and safe. The substantially closed-loop reciprocating diaphragm configuration provides a more efficient transfer of electrical energy to pneumatic energy as compared to prior art valve designs. Also, the reciprocating diaphragm provides inherently safe air flow.

One of the main safety concerns with bladder-type chest compression systems is over-inflation of the bladder. In a reciprocating diaphragm system, there is no net increase in pressure, i.e., the air flow on the in-stroke equals the air flow on the out-stroke. The only way to increase air flow is to increase the diaphragm stroke length or the surface area of the diaphragm. In the present invention, there is no failure mode that could cause either an increased stroke length or increased diaphragm surface area. Conversely, in valve-operated pneumatic devices, a malfunction of a valve may cause unsafe pressures to develop in bladder 2.

Frequency-compensation feedback system 38 serves to maintain the oscillation frequency at the user-selected value. Also, frequency selector 9 is calibrated so that oscillatory air flow generator 15 operates at a maximum oscillation rate as the default value, and frequency selector 9 can only decrease the oscillation frequency. The maximum default oscillation rate is selected to be within safe parameters, therefore, the user cannot increase the oscillation rate to an unsafe level.

Although diaphragm 19 approximates a perfect system in terms of displacement of air into and out of bladder 2 on each stroke, remaining parts of the closed system are less perfect. For example, bladder 2 typically leaks air at a variable rate that is difficult to model. The amount of air leakage is influenced by many factors, including variations in production of the bladder, age, use, and other factors.

Also, tubes 3 and the various connections within the system may also leak. Additionally, the air pressure delivered to bladder 2 must be varied due to the repeated inhalation and expiration of the user during treatment, and also due to the size of the particular user. Therefore, positive air pressure generator 16 is used to supply positive air pressure to the system to compensate for the above-identified variables.

Positive air flow generator 16 includes a blower 48 driven by motor 49. The speed of motor 49 is controlled by pressure-compensation feedback system 50, thereby controlling the output pressure of blower 48.

As shown in FIG. 3, pressure-compensation feedback system 50 is similar to frequency-compensation feedback system 38. The output of pressure transducer 43 is fed through amplifier 44 to a pressure peak detector 51. Peak detector 51 captures the pressure waveform peaks within air chamber 17 and generates a voltage proportional to the pressure peak. This voltage is fed to difference amplifier 52.

Difference amplifier 52 includes a second input 53 representing the user-selected pressure. The difference in actual peak pressure and selected peak pressure is represented in the voltage output of difference amplifier 52 and is fed to pulse-width modulator 54. The output of pulse-width modulator 54 is fed through a second opto-isolator 55 and a second power amplifier 56 on power board 39 to motor 49. Motor 49 drives blower 48 to maintain the peak pressure in air chamber 17 at the user-selected value.

One of ordinary skill in the art will recognize that the pressure in air chamber 17 may also be decreased by a flow of air from air chamber 17 into blower 48, depending on the pressure in air chamber 17 compared to the pressure created by blower 48. In one embodiment, blower 48 may be reversible.

Positive air flow generator 16 and pressure-compensation feedback system 50 provide several advantages. First, positive air flow generator 16 dynamically adjusts the peak pressure in air chamber 17 to provide a consistent peak pressure based on the user selected peak pressure, independent of leaks in the system, size of the user, condition of the bladder, and the repeated inhalation and expiration of the user. Maintaining a constant peak pressure provides for increased efficacy of treatment.

Also, the user only has to make an initial pressure selection, no further interaction with generator 4 is required. The maximum peak pressure setting is selected to be within a safe treatment range. As an additional safety feature, fuse 57 serves to prevent a power surge in power supply 36 from causing blower 48 to inflate bladder 2 to an unsafe pressure.

The circuit for user-operated start/stop control 11 and safety timer 12 are also shown in FIG. 3. In one embodiment, control 11 is a pneumatic switch of known construction. In other embodiments, control 11 may be electronic or electro-mechanical. Actuation of control 11 serves to reset safety timer 12 and also control pulse width modulators 60, 54. The AND gate 61 requires that safety timer 12 be active (i.e., not zero) and control 11 be ON in order for generator 4 to create air pulses.

It is important to note the general ease-of-use provided by the present invention. To initiate treatment, the user simply puts on vest 2 and selects operating parameters on control panel 7, very little training is required. This helps keep down the total cost of the treatment. Also, the user is not required to constantly interact with the device during treatment.

Other embodiments are within the scope of the following claims.

What is claimed is:

1. An apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

an oscillatory air flow generator, comprising

an air chamber;

a reciprocating diaphragm operably connected with the air chamber,

a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;

a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and

a first motor operably connected with the crankshaft;

a continuous air flow generator operably connected with the oscillatory air flow generator;

a first feedback and control means operably connected with the oscillatory air flow generator for maintaining the frequency of the oscillatory air flow generator at a predetermined value;

and a second feedback and control means operably connected with the continuous air flow generator for continuously varying the output pressure of the continuous air flow generator in order to maintain the peak pressure generated by the positive air flow generator at a predetermined value.

2. The apparatus of claim 1 further comprising means for connecting the oscillatory air flow generator with a bladder.

3. The apparatus of claim 1 wherein the first feedback and control means comprises:

means for detecting the oscillation rate in the air chamber;

means for comparing the oscillation rate with the predetermined value; and

means for adjusting the oscillatory air flow generator so that the detected oscillation rate approximately equals the predetermined value.

4. The apparatus of claim 1 further comprising a frequency selector, allowing a user to select the predetermined frequency.

5. The apparatus of claim 1 wherein the continuous air flow generator comprises a blower, and a second motor operably connected with the blower.

6. The apparatus of claim 5 further comprising means connected to the second motor for preventing the second motor from operating the blower above a predetermined pressure.

7. The apparatus of claim 6 wherein the means for preventing comprises a fuse.

8. The apparatus of claim 1 wherein the second feedback and control means comprises:

means for detecting the peak pressure in the air chamber;

means for comparing the detected peak pressure with the predetermined value; and

means for adjusting the continuous air flow generator so that the detected peak pressure equals the predetermined value.

9. The apparatus of claim 1 further comprising a pressure selector, allowing a user to select the predetermined peak pressure.

10. The apparatus of claim 1, further comprising a remote start/stop control operably connected with the first and second feedback and control means.

11. The apparatus of claim 10 further comprises a timer operably connected with the remote start/stop control.

12. The apparatus of claim 1, further comprising a seal extending from an outer periphery of the diaphragm to a wall of the air chamber, the seal comprising first and second generally opposed disks defining an annular region for receiving air, and a pump operably connected with the annular region, the pump maintaining the air pressure in the annular region greater than the peak pressure generated in the air chamber.

* * * * *

United States Patent [19]

Warwick et al.

[11] Patent Number: 4,838,263

[45] Date of Patent: Jun. 13, 1989

[54] CHEST COMPRESSION APPARATUS

[75] Inventors: Warren J. Warwick, Minneapolis; Leland G. Hansen, St. Paul, both of Minn.

[73] Assignee: Regents of the University of Minnesota, St. Paul, Minn.

[21] Appl. No.: 45,888

[22] Filed: May 1, 1987

[51] Int. Cl.[4] A61H 31/00

[52] U.S. Cl. ..... 128/30.2; 128/24 R

[58] Field of Search ..... 128/30, 30.2, 25 R, 128/39, 40, DIG. 20, 28; 272/130; 60/477

[56] References Cited

U.S. PATENT DOCUMENTS

2,588,192	3/1952	Akerman et al.	128/30.2
2,626,601	1/1953	Riley	128/40 X
2,780,222	2/1957	Polzin et al.	128/30.2
2,869,537	1/1959	Jen-chu Chu	128/30.2
3,760,801	9/1973	Borgeas	128/25 R
4,676,232	6/1987	Olsson et al.	128/28

FOREIGN PATENT DOCUMENTS

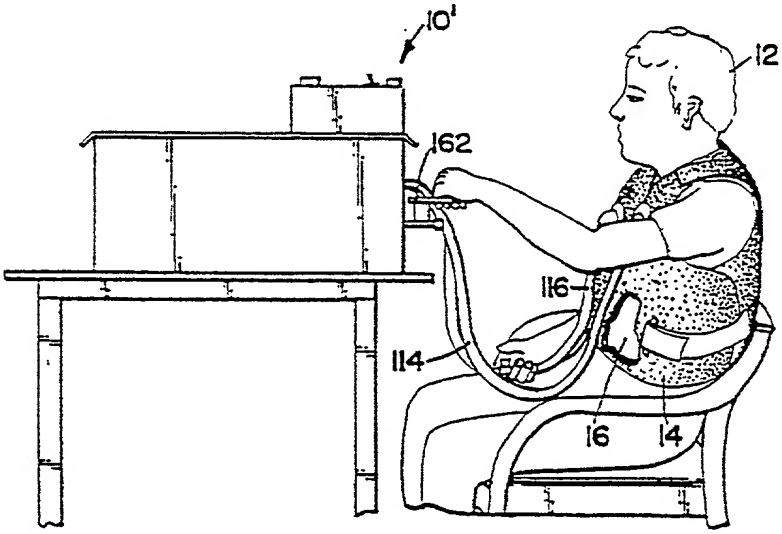
1247009	7/1986	U.S.S.R.	128/30.2

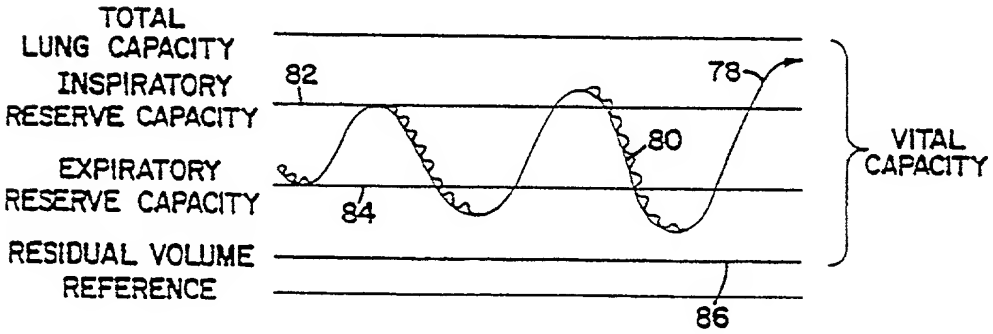
Primary Examiner—Richard J. Apley
Assistant Examiner—Howard Flaxman
Attorney, Agent, or Firm—Merchant, Gould, Smith, Edell, Welter & Schmidt

[57] ABSTRACT

Oscillatory chest compression apparatus to aid in loosening and eliminating mucus from the lungs of a cystic fibrosis patient. The apparatus includes a mechanism for applying pressurized air to a bladder covering the chest of a person and a mechanism for venting pressurized air from the bladder. In addition, the apparatus includes a mechanism for supplying the air to the bladder in a regular pattern of pulses. The application of the pressurized pulses and the pulse rate is controllable by the patient.

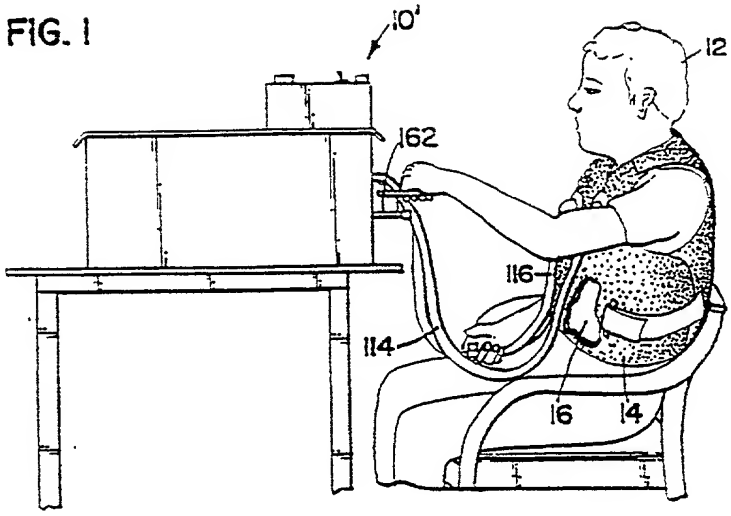
8 Claims, 2 Drawing Sheets





EX. B

FIG. 1


10'
12
162
116
114
16
14

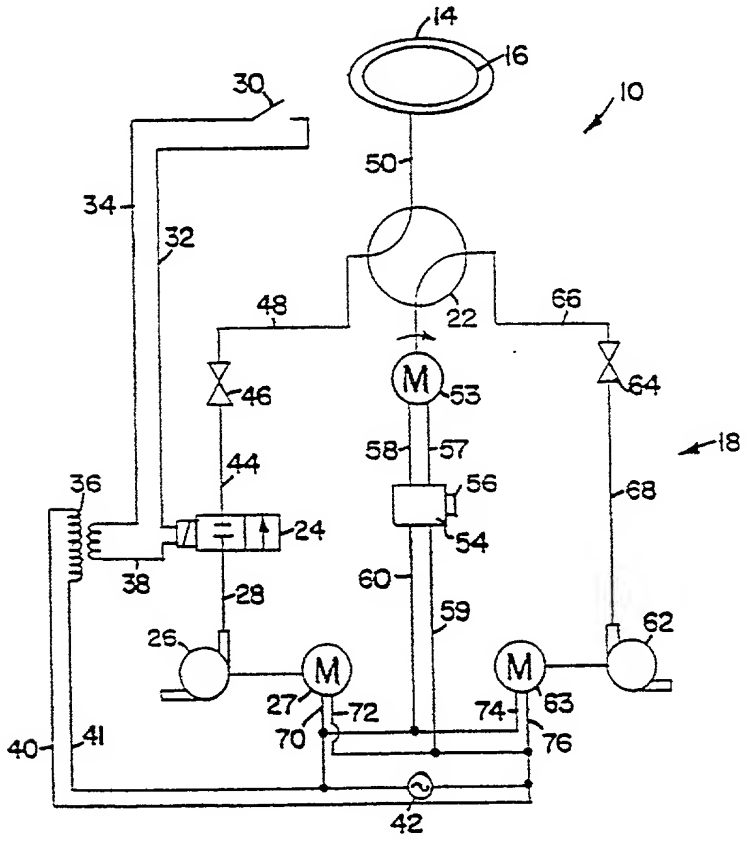
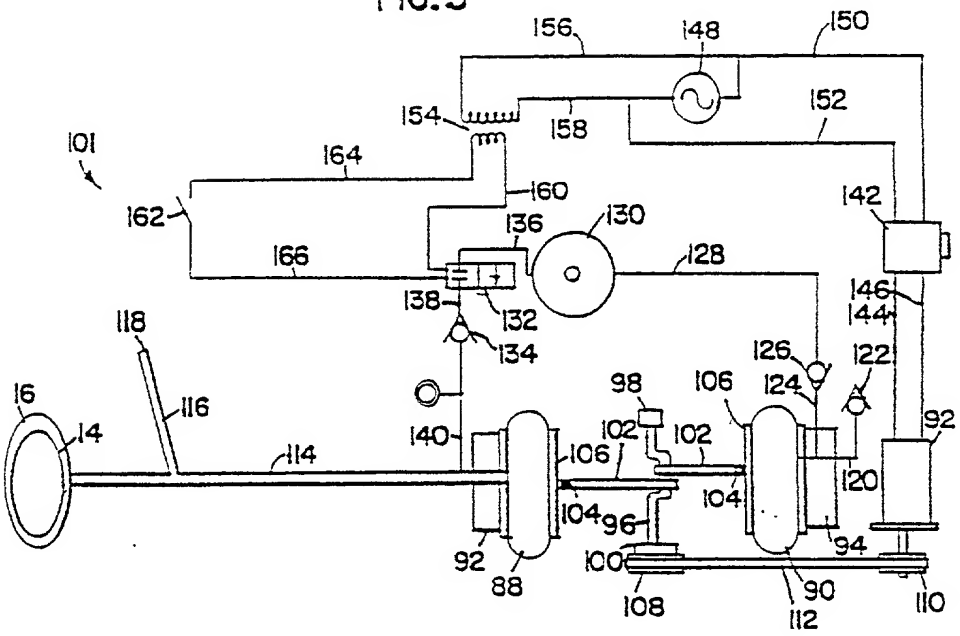

14
16
30
10
50
34
32
48
22
66
46
M
53
64
58
57
18
44
56
68
36
24
54
38
60
28
59
26
62
M
M
27
72
74
63
70
76
40
41
42

FIG. 2

FIG. 3


156
148
150
154
158
152
101
164
160
162
136
130
142
166
128
138
132
146
144
118
134
126
122
16
116
98
106
124
14
140
102
102
92
114
106
120
104
104
96
94
92
88
100
90
110
108
112

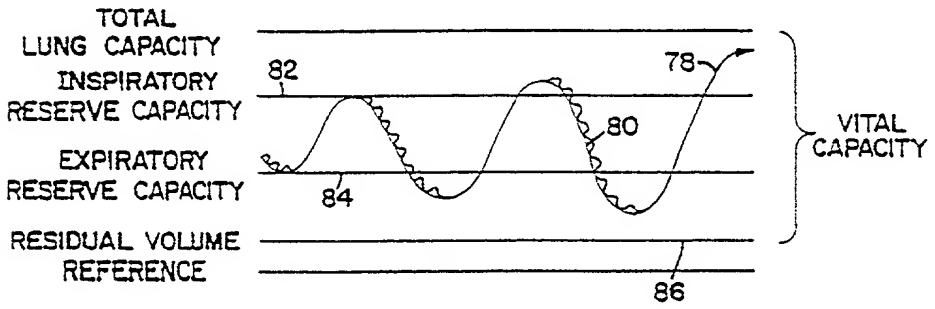

TOTAL LUNG CAPACITY
INSPIRATORY RESERVE CAPACITY
EXPIRATORY RESERVE CAPACITY
RESIDUAL VOLUME REFERENCE
82
78
80
84
86
VITAL CAPACITY

FIG. 4

CHEST COMPRESSION APPARATUS

FIELD OF THE INVENTION

The present invention relates generally to medical devices and, more specifically, to oscillatory chest compression devices which aid in the loosening and elimination of mucus from the lungs of a person, particularly people affected by cystic fibrosis.

BACKGROUND OF THE INVENTION

Cystic fibrosis is a deadly hereditary disease. With one in 20 people carrying the recessive gene, conception of a child having cystic fibrosis results in approximately one in every 400 child-bearing marriages. No cure for the disease has been discovered. Cystic fibrosis affects the mucus secreting glands of the body so that there is an overproduction of mucus. The lungs are continuously filled with the excess mucus, and it must be removed daily to reduce the build-up and the risk of infection. Presently, treatment involves an aerosol therapy three or four times a day to obtain bronchial drainage and a daily physical pounding on the chest wall to loosen mucus for expectoration. Daily treatment can range from four to six hours plus and necessitates a respiratory therapist or at least a trained individual to provide the pummeling of the chest.

The present invention rests on a premise derived from past research with dogs. Oscillating pressure aids mucus clearance in airways and concurrent vibrations decreases the viscosity of the mucus thereby enhancing motility. The research on dogs made use of a modified blood pressure cuff wrapped around the dog in the region of the rib cage. The air bladder in the cuff was pressurized by an oscillating pump.

The art in the area of mechnical vibrations to the body shows such things as inflatable jackets or garments to put on a person to aid in respiration, such as artificial respiration. U.S. Pat. No. 3,043,292, U.S. Pat. No. 2,354,397, U.S. Pat. No. 2,588,192 are representative. Additionally, a garment which provides oscillations for the purpose of messaging the body is shown in U.S. Pat. No. 3,310,050. The art, however, does not address the indicated cystic fibrosis treatment problem.

SUMMARY OF THE INVENTION

The present invention is directed to an oscillatory chest compression apparatus for a person which includes a mechanism for applying a force to the chest of the person. The force applying mechanism includes a bladder for receiving pressurized air. The apparatus also includes a mechanism for supplying a regular pattern of pulses of pressurized air to the bladder, a mechanism for venting the pressurized air from the bladder, and a mechanism for alternately controlling the pulse applying mechanism and the venting mechanism.

In the preferred embodiment, a rotary valve determines the oscillation rate of air entering the bladder from the pressure side and air evacuating the bladder from the depressurizing side. A first blower is used on the pressurizing side of the rotary valve, and a second blower may be used on the evacuation side to rapidly move the air. The bladder is held adjacent to the chest of a person by a shell which is fitted to and fastened about the person. A control switch functions a solenoid valve on the pressurizing side of the rotary valve to stop pressurization during the inspiration portion of the patient's breathing cycle.

In an alternate embodiment, a primary bellows is oscillated to provide air to the bladder adjacent to the chest of the person. In addition, a secondary bellows is oscillated to fill an air reservoir which can rapidly fill the bladder after it has been emptied during an inspiration.

The inventive apparatus is a pioneering solution to the treatment problem faced by people having cystic fibrosis. The advantages of the invention relate to benefits derived from a treatment program utilizing the present apparatus rather than a conventional treatment program. In this regard, a treatment program with the present apparatus provides a cystic fibrosis patient with independence in that the person can operate the machine alone. He/she is no longer required to schedule treatment with a trained individual. This results in increased psychological and physical freedom and self esteem. The person becomes flexible in his/her treatment and can add extra treatments if such would be beneficial as in the case of fighting a common cold. An additional benefit is the vast decrease in cost of treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

The advantages and objectives of the present invention are explained with particularity hereinafter by referring to the drawings briefly described as follows:

FIG. 1 is an illustration of a person operating the alternate embodiment apparatus in accordance with the present invention;

FIG. 2 is a schematic diagram of an apparatus in accordance with the preferred embodiment of the present invention;

FIG. 3 is a schmatic diagram of an apparatus in accordance with the alternate embodiment illustrated in FIG. 1; and

FIG. 4 is an illustration of pressure pulses superimposed on an oscillatory curve representing a patient's breathing cycle.

DETAILED DESCRIPTION OF THE PREFERRED AND ALTERNATE EMBODIMENTS

Referring then to the drawings wherein like reference numerals designate identical or corresponding parts throughout the several views, and more particularly to FIG. 2, an apparatus in accordance with the present invention is designated generally by the numeral 10. With reference to FIG. 1, an alternate embodiment apparatus is designated generally by the numeral 10'. In FIG. 1, person 12 is shown wearing a shell 14 with an air vest or bladder 16 between the shell and his chest. A hose 114 connects the pulse pumping system 18 with vest bladder 16. Person 12 is shown with his left hand regulating switch 162 which controls the supply of air pulses to vest bladder 16, and with his right hand controlling the venting of vest bladder 16 by opening or closing the end of tube 116.

Preferred embodiment 10 could be illustrated similarly to FIG. 1, except is is controllable with only one hand, as will become apparent. As shown in FIG. 2, the air pulse system 18 of apparatus 10 comprises a pair of high volume regenerative blowers 26 and 62 having output which is controlled by a large bore rotary valve 22. The pressure side blower 26 has been tested using a commercially available unit capable of producing a

pressure of 43 inches of water at a volume of 53 cubic feet per minute. Blower 26 is driven by a motor 27. The test unit was driven by a one-half horsepower AC motor at 1725 rpm. The evacuation side blower 62 is driven by a motor 63. The test blower was capable of producing a pressure of 28.5 inches water at a volume capacity of 27 cubic feet per minute. The test blower was operated by a one-eighth horsepower AC motor at 1725 rpm. Preferably, the pressure side blower 26 is oversized relative to the evacuation side blower 62, as indicated with respect to the test units, to accomplish fast reinflation of vest bladder 16 after it has been evacuated.

Alternate positive and negative pressures are applied to vest bladder 16 via a rotary valve 22. During the positive input pulse through valve 22 the negative pressure side of the system is closed. During the negative pressure pulse the positive pressure side of the system is closed. The rotary valve creates alternating positive and negative pressure pulses to vest bladder 16 and is driven by motor 53. During testing, a one-twentieth horsepower DC motor 53 controlled by a conventional DC controller 54 was used. An electronic tachometer with a magnetic pickup was used to monitor valve rotational speed. The blowers operated continuously, so that pulse speed was regulated by controller 54.

A solenoid valve 24 is located between the positive side blower 26 and the rotary valve 22. During testing, solenoid valve 24 has a 1.25 inch bore and was operated by 24 volt power. Valve 24 is normally closed and is controlled by a patient held hand switch 30. In the open position a positive 43 inches of water pressurized air flow is applied to rotary valve 22 which in turn allows the air in the form of a pressure pulse through to vest bladder 16. Since rotary valve 22 opens and closes air flow between positive side blower 26 and vest bladder 16, pulses are created. The pulsing rate is determined by the rotational speed of rotary valve 22 which in turn is determined by motor controller 54.

When solenoid valve 24 is in the closed position, no air flow from the positive side blower 26 passes to vest bladder 16. Rather, vest bladder 16 is evacuated by negative pressure side blower 62. Such evacuation reduces the efforts required by a patient during inhalation. Some patients may find a negative pressure is not needed to evacuate the vest for comfortable inhalation. For such patients, the vacuum or negative pressure blower 62 is optional.

A manual flow valve 46 is located between positive pressure blower 26 and vest bladder 16 to provide adjustment for regulating the flow volume or pulse strength to vest bladder 16. Likewise, a manual flow valve 64 is located between rotary valve 22 and negative side blower 62 to provide control relating to evacuation. That is, for some patients total evacuation of vest bladder 16 may be unnecessary or undesirable. Since rotary valve 22 rotates at a constant speed and since negative side blower 62 operates at a constant speed, when flow valve 64 is set to constrict the flow communication line between rotary valve 22 and blower 62, it will in effect reduce the volume of air which is evacuated during a revolution of rotary valve 22. Therefore, depending on how long the pressure side of apparatus 10 is closed, complete evacuation by the evacuation side may not occur.

With reference to FIG. 2, apparatus 10 is hereinafter described even more particularly. Pressure side blower 26 is in flow communication through hose 28 with normally closed, solenoid valve 24. It is understood that any reference to a hose could as well be a pipe or other mechanism for directing air from one point to another. Solenoid valve 24 is in flow communication with rotary valve 22 through a flow control valve 46, preferably manually operable, wherein hose 44 connects solenoid valve 24 with flow control valve 46 and hose 48 connects flow control valve 46 with rotary valve 22. One or more lines shown as hose 50 connect rotary valve 22 with vest bladder 16. On the negative pressure side, rotary valve 22 is in flow communication through flow control valve 64 with evacuation fan 62. Hose 66 connects rotary valve 22 with flow control valve 64, while hose 68 connects valve 64 with fan 62.

AC motor 27 drives pressurizing fan 26 and is connected via electrical lines 70 and 72 to electrical power source 42. AC motor 63 drives evacuation fan 62 and is connected via lines 74 and 76 to power source 42. DC motor 53 is connected via lines 57 and 58 with controller 54. Controller 54 includes a manual control 56 for varying speed of motor 53. Motor controller 54 receives power via lines 59 and 60 from source 42.

Solenoid valve 24 is connected through an isolation transformer 36 to power source 42. More particularly, solenoid valve 24 is connected to one side of transformer 36 via line 38 and to the other side of transformer 36 via lines 32 and 34 through patient control switch 30. The other side of transformer 36 is connected to power source 42 via lines 40 and 41.

A cystic fibrosis patient is generally weak and has a weak cough and cannot clear mucus from his/her lungs, sometimes hardly at all. A high frequency vibration aids in decreasing the viscosity of the mucus, freeing it from lung walls and thus making it much more likely that a weak cough will be able to clear mucus. As some mucus is cleared, the cough will likely strengthen thereby allowing more and more mucus to be cleared.

A more graphic representation is shown in FIG. 4. The lower frequency line 78 represents the breathing cycle of the patient. The higher frequency line superimposed on portions of the low frequency line represents the pulsing motion administered by vest bladder 16 to the patient's chest.

Initially, the patient breathes rather shallow and uses only a small percentage of his/her total lung capacity as represented by the region between the inspiratory reserve capacity line 82 and the expiratory reserve capacity line 84. As some mucus clears, the patient begins using a greater percentage of his/her lung capacity. A treatment goal is to get the patient breathing so deeply that he/she reduces his/her residual volume as represented by line 86, thereby increasing his/her vital capacity.

To use apparatus 10, first a vest bladder 16 and a shell 14 are custom made for the particular patient 12. The vest bladder 16 must cover the region of the chest which covers the lungs. The vest bladder has a single air chamber with at least one and preferably two air ports located near the upper portion of the chest. The vest, on a test model, was made of 15 mil polyurethane with hook and loop closures in front.

Shell 14 may be any one of several possible types. For example, the hard shell may be made from a polypropylene body cast to have split sides to allow for an easy fit. On the other hand, shell 14 may be made as a soft vest from a non-stretch cloth material. Or, shell 14 may be made of nonstretch cloth material, but made to have front and back panels forming pockets to receive rigid

polyproplyene plates. All shell types preferably include hook and loop closures.

After the patient has been fitted with a vest bladder 16 and shell 14 such that vest bladder conforms to the patient's chest snugly, but not tightly, hose 50 is connected thereto. The three motors 27, 53 and 63 are then turned on. Since solenoid valve 24 is normally closed, fan 26, although operating, is not yet pressurizing vest bladder 16. Evacuation fan 62, also now operating, is functioning to evacuate vest bladder 16. The patient then closes switch 30 which opens solenoid valve 24 and allows for pressurization of vest bladder 16 and does so with air pulses at a frequency set by control 56 of motor controller 54. If the volume of air from either the pressure side or the evacuation side of the system is too great or not enough, hand control valves 46 and 64 are appropriately functioned.

With the system operating, the patient must learn to control apparatus 10 in accordance with his/her breathing cycle. That is, switch 30 must be held down during expiration and released during inspiration so as to provide pulsing during expiration and evacuation during inspiration. The effect is shown graphically in FIG. 4 by the smooth line 78 directed toward inspiratory reserve capacity line 82 and the superimposed wavey line 80 on line 78 directed toward expiratory reserve capacity line 84. The high frequency pulse rate appropriate for any particular patient is obtained by empirically measuring either the flow rate or the volume of air breathed by the patient at different frequencies and at different time durations of the treatment with apparatus 10. The present apparatus is particularly advantageous in this regard since the pulsing frequency can be tuned to a particular patient to optimize energy transmission to the lungs. Typically, the breathing cycle is a relatively low frequency and for a healthy person is commonly about 0.2 to 0.4 hertz. For a person having cystic fibrosis or other sickness, the breathing frequency may range up to one or two hertz. The high frequency pulsing is generally tuned between 10 to 30 hertz and could go as high as the 30 hertz rate for a small child. In any case, the low frequency breathing cycle will be below 5 hertz, while the high frequency pulsing cycle will be above 5 hertz.

It is noted then that the preferred embodiment apparatus provides a patient a number of advantageous features. Compression pulsing is applied to the entire chest. Pulsing frequency may be tuned for optimal energy transmission. Apparatus 10 is patient controlled. If the patient drops switch 30, apparatus 10 simply evacuates pressure.

An alternate embodiment of apparatus 10 is depicted in FIG. 1, as indicated. Apparatus 10' is shown schematically in FIG. 3. The pulse pumping system comprises a pair of bellows 88 and 90 which may be air ride springs of a type commonly used for suspension of large vehicles. Bellows 88 and 90 operate in opposite directions. Bellows 88 and 90 are driven by a one-half horsepower DC electric motor 92 connected by a five millimeter timing belt 112 to a centrally mounted crankshaft 96. The timing belt runs in conjunction with a pair of pulleys 108 and 110. The crankshaft is held in position by bearing pillow blocks 98 and 100. A DC variable speed motor controller 142 is used to regulate motor speed.

The primary bellows 88 is in direct communication with the vest bladder 16 on the patient. Air is compressed in and evacuated out of the vest by the primary bellows at a rate of typically 10 to 30 hertz. The volume of the pulse is calibrated to patient size and is dependent on the length of the pump stroke and the diameter of the bellows.

The secondary bellows 90 provides an additional airflow to vest bladder 16 which allows the patient to regulate vest bladder contact pressure. This has importance since little or no pressure is needed or in fact desired while the chest wall is expanding during inspiration as previously discussed. Therefore, during inspiration air in the vest bladder is vented to atmosphere, and after inspiration a rapid reinstatement of pressure is necessary for effective chest compression before the next breathing cycle begins. The secondary bellows 90 has directional air flow through a series of one way valves to a small air storage tank 130. The pressure of the air storage tank builds to about one psi during patient inspiration, while the air vest bladder 16 vents to atmosphere. The patient regulates the pressure of the vest bladder by covering or uncovering a vent hole on air hose 116 with a finger. When the vent is open, air is vented to atmosphere. When the patient closes the vent hole and also closes switch 162 controlling solenoid valve 132, the compressed air in the air tank is dumped into the inflatable vest bladder. Such action provides quick reinflation of the vest after the patient has finished inhaling to achieve a contact pressure which is efficient for effective oscillatory chest compression.

More particularly, apparatus 10' as shown in FIG. 3 includes primary bellows 88 and secondary bellows 90, both of which are driven by DC motor 92. On the sides facing away from one another, both primary and secondary bellows 88 and 90 are held by identical base members 93 and 94. Each base member 93 and 94 presents a flat solid surface against which the bellows 88 and 90 may be compressed. Crank shaft 96 is supported by bearing pillow blocks 98 and 100. Connecting rods 102 are appropriately attached to crank shaft 96 at one end and at an opposite end may be attached through a universal joint 104 to a plunger 106. It is understood that the present description relates only to functional components and that structural framework is necessary and may be easily envisioned and constructed by one skilled in the art. Pulleys 108 and 110 fasten to crank shaft 96 and the shaft of motor 92, respectively, to support timing belt 112.

Primary bellows 88 is in fluid communication through tube 114 with vest bladder 16. Tube 114 includes a branch tube 116 with an open end 118 which the patient closes when he/she wants pressure in vest bladder 16 and opens when he/she wants to vent vest bladder 16. Secondary bellows 90 receives make up air through tube 120 having a one way check valve 122 open in a flow direction leading toward secondary bellows 90. Secondary bellows 90 is also in fluid communication through tube 124 with one way check valve 126 leading in a flow direction away from secondary bellows 90. Valve 126 is in fluid communication through tube 128 with air storage tank 130. Air storage tank 130 is in fluid communication with tube 114 through solenoid valve 132 and one way valve 134 providing flow only in a direction away from storage tank 130, via tubes 136, 138 and 140. When solenoid valve 132 is open, air from storage tank 130 flows to either or both primary bellows 88 and vest bladder 16. In particular, make up air for primary bellows 88 is supplied by vest bladder 16 or storage tank 130.

Motor 92 is electrically connected with controller 142 via lines 144 and 146. Controller 142 is connected to power source 148 via lines 150 and 152. Solenoid valve

132 is isolated from power source 148 by transformer 154. The primary side of transformer 154 is connected to source 148 via lines 156 and 158. The secondary side of transformer 154 is connected to solenoid valve 132 via line 160 and through patient controlled switch 162 via lines 164 and 166.

To use, as with the preferred embodiment firstly the vest bladder and sheil 16 and 14 are fitted on patient 12. The patient places one hand at the end of tube 116 and the other hand holds switch 162. Motor 92 is started and regulated to a desired speed in a fashion as described with respect to the preferred embodiment apparatus 10' using motor controller 142. The patient must then learn when to apply compression relative to his/her breathing cycle. That is, during expiration, the patient opens switch 162 and closes end 118 of tube 116. During inspiration, it is generally desirable to vent vest bladder 16 so that the patient then opens switch 162 and opens 118 of tube 116.

Thus, although both the preferred and alternate embodiments of apparatus 10 provide pressure pulses to the chest of a patient and allow the patient controls the rate of the pulses and the application of the pulses, it is apparent that the actual components of the two systems are substantially different. In this regard, it is understood then that even though the advantages and details of structure and function of the preferred and alternate embodiments have been set forth, they are nevertheless exemplary and other equivalents are possible. Therefore, changes made, especially in matters of shape, size and arrangement to the full extent extended by the general meaning of the terms in which the appended claims are expressed, are within the principle of the present invention.

What is claimed is:

1. Oscillatory chest compression apparatus for a person, comprising:

means for applying a force to the chest of said person, said force applying means including a bladder for receiving pressurized air;

means for supplying a continuous regular pattern of pulses of said pressurized air to said bladder at a frequency irrespective of and greater than the breathing frequency of said person;

means for venting said pressurized air from said bladder; and

means for controlling said pressurized air in said bladder so that the pressure therein can be increased and decreased in correspondence with the expiration and inspiration breathing frequency of said person wherein said force is applied by said applying means at the pulse frequency of said supplying means with greater impact when said controlling means allows increased air pressure in said bladder and with lessor impact when said controlling means allows decreased air pressure in said bladder.

2. Apparatus in accordance with claim 1 wherein said force applying means also includes a sheil which said person wears to limit outward expansion of said bladder so that said bladder forces inwardly on said person's chest.

3. Apparatus in accordance with claim 1 wherein said pulse supplying means includes a primary bellows;

first means for communicating air between said primary bellows and said bladder;

means for providing air to said primary bellows; and

primary means for reciprocating said primary bellows between expansion and contraction configurations thereby creating pulses of pressurized air.

4. Apparatus in accordance with claim 3 wherein said air providing means includes:

a reservoir for pressurized air;

second means for communicating air in a one-way direction from said reservoir to said primary bellows;

a secondary bellows;

third means for communicating air in a one-way direction from said secondary bellows to said reservoir;

means for inletting air to said secondary bellows; and

secondary means for reciprocating said secondary bellows between expansion and contraction configurations.

5. Appartus in accordance with claim 1 wherein said venting means includes an outlet port, said controlling means including means operable by said person for covering and uncovering said outlet port.

6. Apparatus in accordance with claim 4 wherein said second communicating means includes a one-way valve and said controlling means includes a stop valve installed in said second communicating means and means operable by said person for functioning said stop valve.

7. Apparatus in accordance with clain 1 wherein said pulse supplying means includes:

a pressurizing blower providing a first volume rate of air;

a rotary valve and means for driving said valve;

first means for communicating the air between said pressurizing blower and said rotary valve; and

second means for communicating the air between said rotary valve and said bladder; and wherein said venting means includes:

a depressurizing blower evacuating a second volume rate of air, said second volume rate being less than said first volume rate; and

third means for communicating air from said rotary valve to said depressurizing blower.

8. Apparatus in accordance with claim 7 wherein said controlling means includes a stop valve installed in said first communicating means, said controlling means further including means operable by said person.

* * * * *

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

American Biosystems, Inc.,

Plaintiff,

v.

Civil Action No.

00-2646 DWF/SRN

Electromed, Inc.,

Defendant.

ANSWER TO AMENDED COMPLAINT AND COUNTERCLAIM

For its Answer to the Amended Complaint of Plaintiff American Biosystems, Inc. ("American Biosystems"), Defendant Electromed, Inc. ("Electromed") hereby states as follows:

1. Answer to Paragraph 1 of the Amended Complaint:

Electromed admits that American Biosystems is a Minnesota corporation.

Electromed denies that it is infringing U.S. Patent No. 6,036,662 ("the '662 patent").

Electromed denies that it is infringing U.S. Patent No. 4,838,263 ("the '263 patent").

The remaining statements are not relevant and are denied.

In all other respects, Electromed lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1, and therefore denies the same.

2. Answer to Paragraph 2 of the Amended Complaint:

Electromed manufactures a Medpulse™ Respiratory Vest System which does not use the subject matter of the '662 patent and the '263 patent and does not infringe the '662 patent and the '263 patent. The remaining allegations are vague and indefinite as they do not identify one or more claims of the '662 patent and the '263 patent that are alleged to be infringed by Electromed's Medpulse™ Respiratory Vest System. Electromed admits that it has no license to use American Biosystems' alleged patented technology. Electromed denies that it is utilizing the same type of oscillatory pressure system that is the subject matter of the '662 patent and the '263 patent. Electromed denies that its product infringes any claim of the '662 patent and the '263 patent. Electromed reserves the right to supplement and amend its answer if American Biosystems particularizes its claims alleged in Paragraph 2.

3. Answer to Paragraph 3 of the Amended Complaint:

Electromed lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies such allegations.

4. Answer to Paragraph 4 of the Amended Complaint:

Electromed admits that it is a corporation organized and existing under the laws of Minnesota and denies that its principal place of business is in Minnetonka, Minnesota.

5. Answer to Paragraph 5 of the Amended Complaint:

The allegations of Paragraph 5 state a legal conclusion that does not require an answer. Electromed denies that American Biosystems has any meritorious claim against

it.

6. Answer to Paragraph 6 of the Amended Complaint:

Electromed admits that American Biosystems seeks to invoke the jurisdiction of this Court pursuant to 28 U.S.C. §§ 1331 and 1338.

7. Answer to Paragraph 7 of the Amended Complaint:

Electromed admits that it resides in the District of Minnesota and that American Biosystems alleged that venue is proper in this district. Electromed denies that American Biosystems has any meritorious claim against it. Electromed further denies that it has committed acts of infringement in this district or any other district of the United States of America.

8. Answer to Paragraph 8 of the Amended Complaint:

Electromed admits that a copy of the '662 patent was attached to the Amended Complaint. Electromed denies that the '662 patent was duly and legally issued to American Biosystems, and that this patent is valid or enforceable or has been infringed by Electromed.

In all other respects, Electromed lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 8, and therefore denies such allegations.

9. Answer to Paragraph 9 of the Amended Complaint:

Electromed admits that a copy of the '263 patent was attached to the Amended Complaint.

Electromed denies that the '263 patent was duly and legally granted to the Regents of the University of Minnesota.

Electromed denies that American Biosystems is the exclusive licensee of the '263 patent and has the right to sue alleged infringers of the '263 patent.

In all other respects, Electromed lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 9, and therefore denies such allegations.

10. Answer to Paragraph 10 of the Amended Complaint:

Electromed admits that it manufactures a Medpulse™ Respiratory Vest System.

Electromed denies that the Medpulse™ Respiratory Vest System includes an inflatable vest.

Electromed denies that its Medpulse™ Respiratory Vest System infringes the '662 patent and the '263 patent.

11. Answer to Paragraph 11 of the Amended Complaint:

Electromed denies all allegations of Paragraph 11 of the Complaint unless admitted in the answers to Paragraphs 1 to 10 of the Amended Complaint.

12. Answer to Paragraph 12 of the Amended Complaint:

Electromed denies all allegations of Paragraph 12 of the Amended Complaint.

13. Answer to Paragraph 13 of the Amended Complaint:

Electromed denies all allegations of Paragraph 13 of the Complaint.

14. Answer to Paragraph 14 of the Amended Complaint:

Electromed denies all allegations of Paragraph 14 of the Amended Complaint.

15. Answer to Paragraph 15 of the Amended Complaint:

Electromed denies all of the allegations of Paragraph 15 of the Amended Complaint.

16. Answer to Paragraph 16 of the Amended Complaint:

Electromed denies all of the allegations of Paragraph 16 of the Amended Complaint.

17. Answer to Paragraph 17 of the Amended Complaint:

Electromed denies all allegations of Paragraph 17 of the Amended Complaint unless admitted in the answers to Paragraphs 1 to 16 of the Amended Complaint.

18. Answer to Paragraph 18 of the Amended Complaint:

The allegations of Paragraph 18 of the Amended Complaint are ambiguous and unclear. As understood Electromed denies the allegations of Paragraph 18 of the Amended Complaint.

19. Answer to Paragraph 19 of the Amended Complaint:

Electromed denies the allegations of Paragraph 19 of the Amended Complaint.

20. Answer to Paragraph 20 of the Amended Complaint:

Electromed denies the allegations of Paragraph 20 of the Amended Complaint.

21. Answer to Paragraph 21 of the Amended Complaint:

Electromed denies the allegations of Paragraph 21 of the Amended Complaint.

22. Answer to Paragraph 22 of the Amended Complaint:

Electromed denies the allegations of Paragraph 22 of the Amended Complaint.

AFFIRMATIVE DEFENSES

23. Electromed denies that it has infringed the '662 patent, or actively induced infringement of the '662 patent, or committed any act of contributing infringement of the '662 patent.

24. Because American Biosystems has failed in the Amended Complaint to identify any particular claim or claims of the '662 patent, or any products or practice of Electromed applicable to a claim that is alleged to infringe, Electromed asserts, on information and belief, that the claims of the '662 patent as a whole are invalid for one or more of the reasons set forth below. Electromed reserves the right to supplement and amend these defenses if American Biosystems particularizes its claims and as discovery and trial preparation progress.

25. U.S. Patent No. 6,036,662 is invalid and unenforceable because, inter alia, such patent was not obtained in a manner consistent with and as required by the provisions of Title 35 of the United States Code, in that the '662 patent fails to comply with one or more of the required conditions for patentability for patent claims and specifications (see 35 U.S.C. §§ 102, 103 and 135) and the requirements for patent claims and specifications (see 35 U.S.C. §§ 101 and 112). Under 35 U.S.C. § 282, Electromed shall give notice to American Biosystems of any patent or publication to be relied upon at least thirty days before trial.

26. U.S. Patent No. 6,036,662 is invalid because Claims 1 and 5 contain new matter

prohibited by 35 U.S.C. § 132.

27. American Biosystems is estopped from enforcing claims of the '662 patent as American Biosystems has abandoned claims of the '662 patent and Electromed has relied on the abandonment of these claims.

28. The claims of the '662 patent are also invalid for failure to comply with the requirements of 35 U.S.C. § 112, ¶¶ 1 and 2. Claims of this patent are invalid for failure of the specification to (1) "contain a written description of the invention" and/or (2) contain a written description "of the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112, ¶¶ 1 and 2. Claims of this patent are also invalid for failure to "particularly point[] out and distinctly claim[] the subject matter which" American Biosystems regarded as the invention. 35 U.S.C. § 112, ¶ 2.

29. U.S. Patent No. 6,036,662 is invalid, void, and unenforceable because the patent has been misused by American Biosystems in a wrongful attempt to monopolize the marketing of chest compression devices that are not claimed in the '662 patent and are present in the prior art chest compression devices.

30. American Biosystems does not have a reasonable basis for finding infringement of the '662 patent of Electromed's Medpulse™ Respiratory Vest System or any other product made, used or sold by Electromed.

31. American Biosystems knows, or on a reasonable investigation knows, or should know

that the allegations of infringement of the '662 patent by Electromed are baseless and made in bad faith.

32. U.S. Patent No. 6,036,662 is invalid due to the inequitable conduct of American Biosystems in knowingly withholding relevant prior art and prior art rejections from the U.S. Patent and Trademark Office during the prosecution of the patent application that matured into the '662 patent.

33. American Biosystems is estopped from using the doctrine of equivalents to prove infringement of the '662 patent due to amendments to the claims of the '662 patent.

34. Electromed denies that it has infringed the '263 patent, or actively induced infringement of the '263 patent, or committed any act of contributing infringement of the '263 patent.

35. Because American Biosystems has failed in the Amended Complaint to identify any particular claim or claims of the '263 patent, or any products or practice of Electromed applicable to a claim that is alleged to infringe, Electromed asserts, on information and belief, that the claims of the '263 patent as a whole are invalid for one or more of the reasons set forth below. Electromed reserves the right to supplement and amend these defenses if American Biosystems particularizes its claims and as discovery and trial preparation progress.

36. U.S. Patent No. 4,838,263 is invalid and unenforceable because, inter alia, such patent was not obtained in a manner consistent with and as required by the provisions of Title 35 of the United States Code, in that the '263 patent fails to comply with one or more of the required conditions for patentability for patent claims and specifications (see 35 U.S.C.

§§ 102, 103 and 135) and the requirements for patent claims and specifications (see 35 U.S.C. §§ 101 and 112). Under 35 U.S.C. § 282, Electromed shall give notice to American Biosystems of any patent or publication to be relied upon at least thirty days before trial.

37. The claims of the '263 patent are also invalid for failure to comply with the requirements of 35 U.S.C. § 112, ¶¶ 1 and 2. Claims of this patent are invalid for failure of the specification to (1) "contain a written description of the invention" and/or (2) contain a written description "of the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112, ¶¶ 1 and 2. Claims of this patent are also invalid for failure to "particularly point[] out and distinctly claim[] the subject matter which" American Biosystems regarded as the invention. 35 U.S.C. § 112, ¶ 2.

38. U.S. Patent No. 4,838,263 is invalid, void, and unenforceable because the patent has been misused by American Biosystems in a wrongful attempt to monopolize the marketing of chest compression devices that are not claimed in the '263 patent and are present in the prior art chest compression devices.

39. American Biosystems does not have a reasonable basis for finding infringement of the '263 patent of Electromed's Medpulse™ Respiratory Vest System or any other product made, used or sold by Electromed.

40. American Biosystems knows, or on a reasonable investigation knows, or should know

that the allegations of infringement of the '263 patent by Electromed are baseless and made in bad faith.

41. U.S. Patent No. 4,838,263 is invalid due to the inequitable conduct of American Biosystems in knowingly withholding relevant prior art from the U.S. Patent and Trademark Office during the prosecution of the patent application that matured into the '263 patent.

42. American Biosystems is estopped from using the doctrine of equivalents to prove infringement of the '263 patent due to amendments to the claims of the '263 patent.

COUNTERCLAIMS

Counterclaimant Electromed for its Counterclaim against American Biosystems, alleges as follows:

FIRST COUNTERCLAIM

43. This Counterclaim arises under the patent laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this Counterclaim pursuant to 28 U.S.C. §§ 1331 and 1338, and by reason of the original action filed herein by American Biosystems.

44. This Counterclaim is for declaratory relief under 28 U.S.C. §§ 2201 and 2202.

45. Electromed is a Minnesota corporation with its principal place of business in New Prague, Minnesota.

46. On information and belief, based on allegations in American Biosystems' Amended

Complaint, American Biosystems is a Minnesota corporation.

47. On information and belief, American Biosystems claims to be the owner of the '662 patent asserted by the Amended Complaint in this case.

48. American Biosystems has alleged that Electromed has infringed the '662 patent.

49. Electromed has denied that it has infringed the '662 patent and that the '662 patent is invalid.

50. An actual and justiciable controversy exists between Electromed and American Biosystems as to the validity, enforceability, and infringement of the '662 patent.

51. U.S. Patent No. 6,036,662 has 12 claims.

52. Claim 1 of the '662 patent is the only independent claim in this patent.

53. Claims 2 to 12 are claims that depend on independent Claim 1 and incorporate by reference all the limitations of independent Claim 1.

54. Claim 1 of the '662 patent defines an apparatus for generating oscillatory air pulses in a bladder positioned about a person, comprising:

1) an oscillatory air flow generator, comprising

   a. an air chamber;
   b. a reciprocating diaphragm operably connected with the air chamber;
   c. a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;
   d. a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and
   e. a first motor operably connected with the crankshaft;

2) a continuous air flow generator operably connected with the oscillatory air

flow generator;

3) a first feedback and control means operably connected with the oscillatory air flow generator for maintaining the frequency of the oscillatory air flow generator at a predetermined value;

4) and a second feedback and control means operably connected with the continuous air flow generator for continuously varying the output pressure of the continuous air flow generator in order to maintain the peak pressure generated by the positive air flow generator at a predetermined value.

55. The Electromed Medpulse™ Respiratory Vest System alleged by American Biosystems to infringe the '662 patent does not have:

1) c. a rod having a first end and a second end, the first end operably connected with the diaphragm, and the rod extending generally orthogonal to the diaphragm;

1) d. a crankshaft operably connected with the second end of the rod and extending generally orthogonal to the rod; and

1) e. a first motor operably connected with the crankshaft;

as defined in Claim 1 of the '662 patent.

56. The Electromed Medpulse™ Respiratory Vest System alleged by American Biosystems to infringe the '662 patent does not have:

2) a continuous air flow generator operably connected with the oscillatory air flow generator;

as defined in Claim 1 of the '662 patent.

57. The Electromed Medpulse™ Respiratory Vest System alleged by American Biosystems to infringe the '662 patent does not have:

3) a first feedback and control means operably connected with the oscillatory air flow generator for maintaining the frequency of the oscillatory air flow

generator at a predetermined value;

as defined in Claim 1 of the '662 patent.

58. The Electromed Medpulse™ Respiratory Vest System alleged by American Biosystems to infringe the '662 patent does not have:

> 4) and a second feedback and control means operably connected with the continuous air flow generator for continuously varying the output pressure of the continuous air flow generator in order to maintain the peak pressure generated by the positive air flow generator at a predetermined value.

as defined in Claim 1 of the '662 patent.

59. American Biosystems has been advised that Electromed's respiratory vest system does not have the structures and functions claimed in Claim 1 of the '662 patent as listed in Paragraphs 55 to 58 herein and does not infringe the '662 patent.

60. There is no reasonable basis for finding infringement of the '662 patent by Electromed's making, using and selling its Medpulse™ Respiratory Vest System and bringing a claim of infringement of the '662 patent.

61. American Biosystems knows, or on a reasonable investigation knows, or should know that the allegation of infringement of the '662 patent by Electromed's Medpulse™ Respiratory Vest System is baseless.

62. American Biosystems has been advised that the basis in fact for its allegation of patent infringement by Electromed is without merit or foundation and is groundless, frivolous, made in bad faith, or for an improper purpose.

63. American Biosystems has instigated this infringement civil action against Electromed in

bad faith and without just cause and in pursuance of a policy to drive Electromed out of business and to monopolize the business of oscillatory chest compression devices throughout the United States of America. American Biosystems' civil action against Electromed, was willfully committed, for purposes of harassment and oppression, with the object of alienating investors, customers and potential customers, and with the intent to subject Electromed to financial hardship, not only for substantial expenses of litigation, but also resulting in substantial loss of sales and profits.

64. American Biosystems having instigated this vexatious and expensive infringement suit herein against Electromed, may dismiss such suit without adjudication of the '662 patent, thereby leaving Electromed and the public subject to further annoyance and litigation.

65. That it is necessary by virtue of the various contentions hereinabove set forth, for the Court to determine and define the rights of the parties hereto in respect thereto.

66. Electromed avers that unless Electromed is found not to infringe the '662 patent or if said patent is not adjudged to be void and invalid, Electromed will be harassed in the manufacture, sale and use of its products.

SECOND COUNTERCLAIM

67. This Counterclaim arises under the patent laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this Counterclaim pursuant to 28 U.S.C. §§ 1331 and 1338, and by reason of the original action filed herein by American Biosystems.

68. This Counterclaim is for declaratory relief under 28 U.S.C. §§ 2201 and 2202.

69. Electromed is a Minnesota corporation with its principal place of business in New Prague, Minnesota.

70. On information and belief, based on allegations in American Biosystems' Amended Complaint, American Biosystems is a Minnesota corporation.

71. On information and belief, the Regents of the University of Minnesota are the owners of U.S. Patent No. 4,838,263 issued June 13, 1989 titled Chest Compression Apparatus.

72. On information and belief, based on allegations in American Biosystems' Amended Complaint, American Biosystems claims to have a license from the Regents of the University of Minnesota to make, use, and sell chest compression apparatus as disclosed and claimed in the '263 patent.

73. American Biosystems has alleged in the Amended Complaint that Electromed has infringed the '263 patent.

74. Electromed has denied that it has infringed the '263 patent and that the '263 patent is invalid.

75. An actual and justiciable controversy exists between Electromed and American Biosystems as to the validity, enforceability, and infringement of the '263 patent.

76. American Biosystems has been advised that Electromed's respiratory vest system does not have the structures and functions claimed in Claim 1 of the '263 patent.

77. There is no reasonable basis for finding infringement of the '263 patent by Electromed's making, using and selling its Medpulse™ Respiratory Vest System and bringing a claim

of infringement of the '263 patent.

78. American Biosystems knows, or on a reasonable investigation knows, or should know that the allegation of infringement of the '263 patent by Electromed's Medpulse™ Respiratory Vest System is baseless.

79. American Biosystems has instigated this infringement civil action against Electromed in bad faith and without just cause and in pursuance of a policy to drive Electromed out of business and to monopolize the business of oscillatory chest compression devices throughout the United States of America. American Biosystems' civil action against Electromed, was willfully committed, for purposes of harassment and oppression, with the object of alienating investors, customers and potential customers, and with the intent to subject Electromed to financial hardship, not only for substantial expenses of litigation, but also resulting in substantial loss of sales and profits.

80. American Biosystems having instigated this vexatious and expensive infringement suit herein against Electromed, may dismiss such suit without adjudication of the '263 patent, thereby leaving Electromed and the public subject to further annoyance and litigation.

81. That it is necessary by virtue of the various contentions hereinabove set forth, for the Court to determine and define the rights of the parties hereto in respect thereto.

82. Electromed avers that unless Electromed is found not to infringe the '263 patent or if said patent is not adjudged to be void and invalid, Electromed will be harassed in the manufacture, sale and use of its products.

THIRD COUNTERCLAIM

83. This Counterclaim arises under the trademark laws of the United States, Title 15, Chapter 22, §§ 1125 and 1117.

84. This Court has jurisdiction over the subject matter of this Counterclaim pursuant to 28 U.S.C. §§ 1331 and 1338, and by reason of the original action filed herein by American Biosystems.

85. This Counterclaim is for declaratory relief under 28 U.S.C. §§ 2201 and 2202. Electromed is a Minnesota corporation with its principal place of business in New Prague, Minnesota.

86. American Biosystems is a corporation of Minnesota with its place of business in St. Paul, Minnesota.

87. Electromed is a Minnesota corporation having a place of business in New Prague, Minnesota.

88. American Biosystems has published advertising stating that "the ABI Vest Airway Clearance System is covered by U.S. Patents 5,769,797; 4,838,263; 4,977,889; and 5,056,505."

89. On information and belief, the Model 103 and other ABI Vest Airway Clearance System are not covered by one or more of U.S. Patents 5,769,797; 4,838,263; 4,977,889; and 5,056,505.

90. The statement published by American Biosystems that "the ABI Vest Airway Clearance System is covered by U.S. Patents 5,769,797; 4,838,263; 4,977,889; and 5,056,505" is a misleading representation of fact that misrepresents the nature and characteristics of the

ABI Vest Airway Clearance System and is false advertising.

91. American Biosystems has willfully engaged in the trade practice set out in Paragraph 88 knowing it to be deceptive.

92. Electromed is likely to be damaged and has been damaged by American Biosystems willful deceptive trade practices in an amount to be determined.

93. American Biosystems has made substantial profits form the marketing of the ABI Vest Airway Clearance System.

94. That it is necessary by virtue of the various contentions hereinabove set forth, for the Court to determine and define the rights of the parties hereto in respect thereto.

95. Electromed avers that American Biosystems will continue with its unfair trade practices to mislead the public and cause damage to Electromed.

FOURTH COUNTERCLAIM

96. This Counterclaim arises under Minnesota Statutes § 325D.43-48, Deceptive Trade Practices.

97. This Court has jurisdiction over the subject matter of this Counterclaim pursuant to 28 U.S.C. §§ 1331, 1338 and 1367 as Electromed's deceptive trade practices claim is related to Electromed's claim of violation of 15 U.S.C. § 1125.

98. This Counterclaim is for declaratory relief under 28 U.S.C. §§ 2201 and 2202.

99. Electromed is a Minnesota corporation with its principal place of business in New Prague, Minnesota.

100. American Biosystems is a corporation of Minnesota with its place of business in St. Paul, Minnesota.

101. American Biosystems has published advertising stating that "the ABI Vest Airway Clearance System is covered by U.S. Patents 5,769,797; 4,838,263; 4,977,889; and 5,056,505."

102. On information and belief, the Model 103 and other ABI Vest Airway Clearance System are not covered by one or more of U.S. Patents 5,769,797; 4,838,263; 4,977,889; and 5,056,505.

103. The statement published by American Biosystems that "the ABI Vest Airway Clearance System is covered by U.S. Patents 5,769,797; 4,838,263; 4,977,889; and 5,056,505" is a misleading representation of fact that misrepresents the nature and characteristics of the ABI Vest Airway Clearance System and is false advertising.

104. American Biosystems has willfully engaged in the trade practice set out in Paragraph 88 knowing it to be deceptive.

105. Electromed is likely to be damaged and has been damaged by American Biosystems willful deceptive trade practices in an amount to be determined.

106. American Biosystems has made substantial profits form the marketing of the ABI Vest Airway Clearance System.

107. That it is necessary by virtue of the various contentions hereinabove set forth, for the Court to determine and define the rights of the parties hereto in respect thereto.

108. Electromed avers that American Biosystems will continue with its unfair trade practices

to mislead the public and cause damage to Electromed.

FIFTH COUNTERCLAIM

109. This Counterclaim arises under the patent laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this Counterclaim pursuant to 28 U.S.C. §§ 1331 and 1338, and by reason of the original action filed herein by American Biosystems.

110. This Counterclaim is for declaratory relief under 28 U.S.C. §§ 2201 and 2202.

111. American Biosystems is a corporation of Minnesota having a place of business in St. Paul, Minnesota.

112. Electromed is a Minnesota corporation having a place of business in New Prague, Minnesota.

113. American Biosystems is the owner of U.S. Patent Application Serial No. 09/039,606 and U.S. Patent 6,036,662 issued from this patent application.

114. U.S. Patent 6,036,662 is a continuation of U.S. Patent 5,769,797 owned by American Biosystems which issued from U.S. Patent Application Serial No. 08/661,931 and contains the identical disclosure as Application Serial No. 09/039,606.

115. Claim 1 of Application Serial No. 08/661,931 was rejected by the U.S. Patent and Trademark Office under 35 U.S.C. § 102(e) as being anticipated by Hansen (U.S. Patent 5,453,081).

116. Claim 1 of Application Serial No. 08/661,931 was amended by the applicants to

distinguish from the Hansen patent by adding a reciprocating diaphragm, rod and crankshaft, and a motor connected to a crankshaft.

117. Claim 1 was further amended by the patent examiner with the approval of the applicants to include a seal having an annular region around the diaphragm, and pump to maintain air pressure in the annular region of the seal.

118. The Electromed Medpulse Respiratory Vest System does not include a seal with an annular region around the diaphragm and a pump to maintain air pressure in the annular region of the seal as claimed in U.S. Patent 5,769,797 and American Biosystems has not claimed infringement of U.S. Patent 5,769,797.

119. American Biosystems by amending Claim 1 of Patent Application Serial No. 08/661,931 has abandoned the apparatus for generating oscillatory air pulses in a bladder defined in original Claim 1 of Application Serial No. 08/661,931.

120. Electromed relied on the amendments and abandonment of claims in Application Serial No. 08/661,931.

121. American Biosystems in Application Serial No. 09/039,606 failed to advise the U.S. Patent and Trademark Office of the rejection of Claim 1 as anticipated by the Hansen patent and failed to make all of the prior art references of record in Application Serial No. 08/661,931 of record for consideration by the patent examiner.

122. American Biosystems in amending Claims 1 and 15 of Application Serial No. 09/039,606 added new matter to these claims contrary to 35 U.S.C. § 132.

123. In view of the inequitable actions of American Biosystems noted in Paragraphs 121 and

122, the amendments and abandonment of claims in Application Serial No. 08/661,931, and limitation of claims of U.S. Patent 5,769,797 relied on by Electromed to proceed with the Electromed Medpulse™ Respiratory Vest System and the limitations in U.S. Patent 5,769,797 and proceeded with its development and marketing of the Electromed Medpulse™ Respiratory Vest System without interference with U.S. Patent 5,769,797.

124. American Biosystems has unclean hands which renders the '662 patent unenforceable with respect to Electromed.

PRAYER FOR RELIEF

Wherefore, Defendant Electromed, Inc. prays for the following judgment and relief:

A. That the Complaint be dismissed with prejudice;

B. That American Biosystems take nothing by its Complaint;

C. That American Biosystems claim for injunctive relief be denied;

D. That it be declared Electromed does not infringe U.S. Patent No. 6,036,662;

E. That U.S. Patent No. 6,036,662 be declared invalid;

F. That U.S. Patent No. 6,036,662 be declared unenforceable;

G. That it be declared Electromed does not infringe U.S. Patent No. 4,838,263;

H. That U.S. Patent No. 4,838,263 be declared invalid;

I. That U.S. Patent No. 4,838,263 be declared unenforceable;

J. That American Biosystems has violated 15 U.S.C. § 1125;

K. That Electromed be awarded American Biosystems profits for the years 2000 and 2001;

L. That American Biosystems has violated Minnesota Statutes § 325D.43-48, Deceptive Trade Practices;

M. That Electromed be awarded reasonable costs and attorneys' fees pursuant to Minnesota Statutes § 325D.45;

N. That Electromed be awarded damages of at least $500,000;

O. That Electromed be awarded reasonable costs and attorneys' fees pursuant to 35 U.S.C. § 285 and/or 28 U.S.C. § 1927.

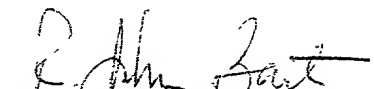
P. That Electromed be granted all other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Electromed sets forth its demand for a jury trial on all issues for which it is entitled for a jury trial.

Dated: July 11, 2001

Respectfully submitted,



Richard O. Bartz #5174
Richard John Bartz #166364
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435
(952) 920-3959

Attorneys for Defendant
Electromed, Inc.

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	**Civil Action No. 00-2646 DWF/SRN** **REPLY TO AMENDED COUNTERCLAIMS** *Jury Trial Demanded*

Plaintiff American Biosystems, Inc. ("American Biosystems") for its Reply to Defendant Electromed, Inc.'s ("Electromed") Amended Counterclaims states:

FIRST COUNTERCLAIM

1. Admits the allegations in paragraph 43 of defendant's counterclaim.

2. Admits that Electromed is seeking declaratory relief under 28 U.S.C. § 2201 and 2202 but denies that such relief as requested is proper.

3. Admits that Electromed is a Minnesota Corporation but lacks sufficient information to admit or deny the remaining allegations of paragraph 45 and therefore, denies the same.

4. Admits that American Biosystems, Inc. is a Minnesota Corporation as alleged in paragraph 46 of defendant's counterclaims.

5. Admits the allegations in paragraph 47 of defendant's counterclaims.

6. Admits the allegations in paragraph 48 of defendant's counterclaims.

7. Admits the allegations contained in paragraph 49 of defendant's counterclaims.

8. Admits that Electromed is contesting the validity, unenforceability, and infringement of the '662 patent but denies the remaining allegations contained in paragraph 50 of defendant's counterclaims.

9. Admits that an actual and justiciable controversy exists between Electromed and American Biosystems as to the asserted claims of the '662 patent but denies the remaining allegations contained in paragraph 50 of defendant's counterclaims, if any.

10. Alleges that the document referenced in paragraph 51 of defendant's counterclaims speaks for itself.

11. Alleges that the document referenced in paragraph 52 of defendant's counterclaims speaks for itself.

12. Alleges that the document referenced in paragraph 53 of defendant's counterclaims speaks for itself.

13. Alleges that the document referenced in paragraph 54 of defendant's counterclaims speaks for itself.

14. Denies the allegations contained in paragraph 55 of defendant's counterclaims.

15. Denies the allegations contained in paragraph 56 of defendant's counterclaims.

16. Denies the allegations contained in paragraph 57of defendant's counterclaims.

17. Denies the allegations contained in paragraph 58 of defendant's counterclaims.

18. Admits that defendant has alleged that its respiratory vest system does not have the structures and functions claimed in claim 1 of the '662 patent and that the vest system does not infringe the '662 patent and admits that defendant has denied infringement in a letter to American Biosystems, but denies the remaining allegations, if any, in paragraph 59 of defendant's counterclaims, and specifically alleges that defendant's vest system does have the

structures and functions claimed in claim 1 of the '662 patent as listed in paragraphs 55-58 of defendant's counterclaims and infringes the '662 patent.

19. Denies the allegations contained in paragraph 60 of defendant's counterclaims.

20. Denies the allegations contained in paragraph 61 of defendant's counterclaims.

21. Admits that defendant has alleged that American Biosystems patent infringement suit is without merit or foundation and is groundless, frivolous, made in bad faith, or for an improper purpose and admits that defendant has so stated in a letter to American Biosystems, but denies the remaining allegations, if any, in paragraph 62 of defendant's counterclaims.

22. Denies the allegations contained in paragraph 63 of defendant's counterclaims and states that American Biosystems has brought this action against Electromed for the proper purpose of adjudicating American Biosystems patent rights.

23. Denies the allegations contained in paragraph 64 of defendant's counterclaims.

24. Denies the allegations contained in paragraph 65 of defendant's counterclaims except admits that the court has jurisdiction over the claims of the '662 patent that are asserted by American Biosystems.

25. Denies the allegations contained in paragraph 66 of defendant's counterclaims.

SECOND COUNTERCLAIM

26. Admits the allegations in paragraph 67 of defendant's counterclaims.

27. Admits that Electromed is seeking declaratory relief under 28 U.S.C. § 2201 and 2202 but denies that such relief as requested is proper.

28. Admits that Electromed is a Minnesota Corporation but lacks sufficient information to admit or deny the remaining allegations of paragraph 69 and therefore, denies the same.

29. Admits that American Biosystems, Inc. is a Minnesota Corporation as alleged in paragraph 70 of defendant's counterclaims.

30. Admits that the Regents of the University of Minnesota are the assignee of U.S. Patent No. 4,838,263 issued June 13, 1989 titled Chest Compression Apparatus, but otherwise denies the remaining allegations contained in paragraph 71 of defendant's counterclaims.

31. Admits the allegations contained in paragraph 72 of defendant's counterclaims.

32. Admits the allegations contained in paragraph 73 of defendant's counterclaims.

33. Admits the allegations contained in paragraph 74 of defendant's counterclaims.

34. Admits that an actual justiciable controversy exists between Electromed and American Biosystems as to the asserted claims of the '263 patent but denies the remaining allegations contained in paragraph 75 of defendant's counterclaim, if any.

35. Admits that Electromed has alleged that its respiratory vest systems do not have the structures and functions claimed in claim 1 of the '263 patent but denies the remaining allegations, if any, in paragraph 76 of defendant's counterclaims, and specifically states that defendant's vest system does have the structures and functions claimed in claim 1 of the '263 patent and infringes the '263 patent.

36. Denies the allegations contained in paragraph 77 of defendant's counterclaims.

37. Denies the allegations contained in paragraph 78 of defendant's counterclaims.

38. Denies the allegations contained in paragraph 79 of defendant's counterclaims.

39. Denies the allegations contained in paragraph 80 of defendant's counterclaims.

40. Denies the allegations contained in paragraph 81 of defendant's counterclaims except that admits that the court has jurisdiction over the claims of the '263 patent that are asserted by American Biosystems.

41. Denies the allegations contained in paragraph 82 of defendant's counterclaims.

THIRD COUNTERCLAIM

42. Admits that defendant Electromed purports to invoke the Trademark Laws of the United States, Title 15, Chapter 22, Sections 1125 and 1117, But denies that any claims exists under those statutes.

43. With respect to paragraph 84 of defendant's counterclaims, admits that the court has jurisdiction over the subject matter; denies that the counterclaim states a claim upon which relief can be granted.

44. Admits that defendant Electromed is purporting to assert a counterclaim for declaratory relief under 28 U.S.C. §§ 2201 and 2202 and that Electromed is a Minnesota Corporation but lacks sufficient information to form a belief as to the truth of the remaining allegations in paragraph 85 of defendant's counterclaim and denies the same.

45. Admits that American Biosystems is a Minnesota corporation as alleged in paragraph 86 of defendant's counterclaims.

46. Admits the allegations contained in paragraph 87 of defendant's counterclaims.

47. Alleges that any document referenced paragraph 88 of defendant's counterclaims speaks for itself.

48. Denies that any of U.S. Patents 5,769,797; 4,838,263; 4,977,889; and 5,056,505 do not cover any "ABI Vest Airway Clearance System" and lacks sufficient information so as to form a belief as to the truth of the remaining allegations in paragraph 89 of defendant's counterclaims and therefore denies the same.

49. Denies the allegations contained in paragraph 90 of defendant's counterclaims.

50. Denies the allegations contained in paragraph 91 of defendant's counterclaims.

51. Denies the allegations contained in paragraph 92 of defendant's counterclaims.

52. Denies the allegations contained in paragraph 93 of defendant's counterclaims.

53. Denies that there is any virtue to the various contentions set forth in this counterclaim and further denies that Electromed has any rights by virtue of these contentions and denies the remaining allegations contained in paragraph 94 of defendant's counterclaims.

54. Denies the allegations contained in paragraph 95 of defendant's counterclaims.

FOURTH COUNTERCLAIM

55. Denies the allegations contained in paragraph 96 of defendant's counterclaims.

56. Denies that Electromed has any deceptive trade practices claim and therefore, denies the remaining allegations contained in paragraph 97 of defendant's counterclaims.

57. Admits that Electromed purports to be seeking declaratory relief but denies that any counterclaim exists and therefor, denies the remaining allegations contained in paragraph 98 of defendant's counterclaims.

58. Admits the allegations contained in paragraph 99 of defendant's counterclaims.

59. Admits that American Biosystems is a Minnesota corporation as alleged in paragraph 100 of defendant's counterclaims.

60. Alleges that any document referenced in paragraph 101 of defendant's counterclaims speaks for itself.

61. Denies that any of U.S. Patents 5,769,797; 4,838,263; 4,977,889; and 5,056,505 do not cover any "ABI Vest Airway Clearance System" and lacks sufficient information so as to form a belief as to the truth of the remaining allegations in paragraph 102 of defendant's counterclaims and therefore denies the same.

62. Denies the allegations contained in paragraph 103 of defendant's counterclaims.

63. Denies the allegations contained in paragraph 104 of defendant's counterclaims.

64. Denies the allegations contained in paragraph 105 of defendant's counterclaims.

65. Denies the allegations contained in paragraph 106 of defendant's counterclaims.

66. Denies that there is any virtue to the various contentions set forth in this counterclaim and further denies that Electromed has any rights by virtue of these contentions and denies the remaining allegations contained in paragraph 107 of defendant's counterclaims.

67. Denies the allegations contained in paragraph 108 of defendant's counterclaims.

FIFTH COUNTERCLAIM

68. Denies that any counterclaim exists by virtue of the allegations set forth and therefore, denies the remaining allegations of paragraph 109 of defendant's counterclaims.

69. Admits that defendant is purporting to seek declaratory relief but denies that any claim exists and therefore denies the remaining allegations of paragraph 110 of defendant's counterclaims.

70. Admits the allegations contained in paragraph 111 of defendant's counterclaims.

71. Admits the allegations contained in paragraph 112 of defendant's counterclaims.

72. Admits that American Biosystems is the assignee of U.S. Patent Application Serial Number 09/039,606 and that U.S. Patent 6,036,662 issued from that patent application.

73. Alleges that the documents referenced in paragraph 114 of defendant's counterclaims speak for themselves.

74. Alleges that the documents referenced in paragraph 115 of defendant's counterclaims speak for themselves.

75. Alleges that the documents referenced in paragraph 116 of defendant's counterclaims speak for themselves.

76. Alleges that the documents referenced in paragraph 117 of defendant's counterclaims speak for themselves.

77. Lacks sufficient information as to form a belief as to the truth of the allegations contained in paragraph 118 of defendant's counterclaims and therefore denies the same except that admits that American Biosystems has not claimed infringement of U.S. Patent 5,769,797.

78. Denies the allegations contained in paragraph 119 of defendant's counterclaims.

79. Lacks sufficient information to form a belief as to the truth of the allegations contained in paragraph 120 of defendant's counterclaims and therefore denies the same.

80. Lacks sufficient information to form a belief as to the truth of the allegations contained in paragraph 121 of defendant's counterclaim and therefore denies the same.

81. Denies the allegations contained in paragraph 122 of defendant's counterclaims.

82. Denies that American Biosystems undertook any inequitable actions as alleged in paragraphs 121 and 122 of defendant's counterclaims and lacks sufficient information to form a belief as to the truth of the remaining allegations contained in paragraph 123 of defendant's counterclaims and therefore denies the same.

83. Denies the allegations contained in paragraph 124 of defendant's counterclaims.

84. Except as admitted, alleged or otherwise quantified hereinabove, denies each and every allegation contained in defendant's counterclaims.

85. The counterclaims fail to state a claim upon which relief can be granted.

AFFIRMATIVE DEFENSES

86. U.S. Patent No. 6,036,662 is valid, enforceable, and infringed by Electromed's respiratory vest system.

87. U.S. Patent No. 4,838,263 is valid, enforceable, and infringed by Electromed's respiratory vest system.

88. Any harm or damage suffered by defendant was caused by defendant or others over whom ABI has no control.

89. To the extent defendant purports to plead fraud, it has failed to do so with particularity.

90. The counterclaims are barred by the doctrines of laches, waiver, estoppel or acquiescence.

91. The counterclaims are barred by the relevant statute of limitations.

92. Any statements made by American Biosystems, even if false, were not materially deceptive.

93. The counterclaims are barred by the doctrine of unclean hands.

PRAYER FOR RELIEF

American Biosystems prays that:

1. It be granted the relief sought in the Complaint;

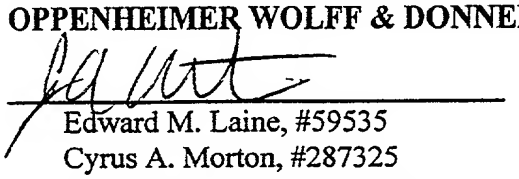
2. Electromed's counterclaims be dismissed with prejudice and on the merits and Electromed shall take nothing by its counterclaims;

3. American Biosystems be awarded its costs, disbursements and attorneys' fees; and,

4. American Biosystems be awarded such further relief, as the court may deem just and equitable.

Dated: August 3, 2001

OPPENHEIMER WOLFF & DONNELLY LLP



Edward M. Laine, #59535
Cyrus A. Morton, #287325
David J. McKinley, #295814
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, Minnesota 55402-1609
Telephone: (612) 607-7000
Facsimile: (612) 607-7100

ATTORNEYS FOR PLAINTIFF AMERICAN BIOSYSTEMS, INC.

UNITED STATES DISTRICT COURT
District of Minnesota

American Biosystems, Inc., Plaintiff, vs. Electromed, Inc. Defendant.	Case Number: 00-2646 DWF/SRN **STIPULATION AND ORDER TO MODIFY THE FEBRUARY 22, 2001 PRETRIAL SCHEDULING ORDER**

Pursuant to Local Rule 16.3., the parties, through their respective undersigned attorneys, hereby stipulate and agree that the Pretrial Scheduling Order may be amended as attached.

Date: August 30, 2001

OPPENHEIMER WOLFF & DONNELLY LLP

By _____

Edward M. Laine, #59535
Cyrus A. Morton, #287325
David J. McKinley, #295814
Plaza VII, Suite 3300
45 South Seventh Street
Minneapolis, MN 55402
Phone: (612) 607-7000
Fax No.: (612) 607-7100

ATTORNEYS FOR PLAINTIFF

Dated: August 30, 2001

BARTZ & BARTZ

By _____

Richard O. Bartz, #5174
R. John Bartz, #166364
Southdale Office Centre
6750 France Avenue South
Suite 350
Edina, MN 55435
Telephone: (612) 920-3959
Facsimile: (612) 920-6494

ATTORNEYS FOR DEFENDANT

contends are absent. In the latter regard, defendant will set forth in detail the basis for its contention that the element is absent.

a. In the case of a disputed element written in means plus function form, Defendant shall state what it believes the disclosed structure is and state the basis of its contention that the disclosed structure or its equivalent is not present in the accused device.

b. As to the doctrine of equivalents, defendant shall indicate on its chart each of its contentions that any differences between the claim element and the accused disputed device are substantial.

3. Following Defendant's service of its Claim Chart as set forth above, the Court shall be contacted for purposes of scheduling a hearing to determine claim interpretation. ("Markman Hearing")

a. Forty-five (45) days in advance of the Markman hearing date, each side shall file with the court a statement of the interpretation for which it contends, along with a memorandum explaining how the intrinsic evidence (claims, specification and prosecution history of the patent(s)-in-suit) support that interpretation.

b. If either side alleges that it also intends to rely on extrinsic evidence, it shall:

(i) explain why extrinsic evidence is necessary;
(ii) explain the extrinsic evidence it intends to offer; and
(iii)if the extrinsic evidence is testimony (e.g., from an expert of the inventor), submit to the court such testimony in the form of an affidavit.

c. If one side indicates its intention to reply on extrinsic evidence, within 15 days the opposite party shall file a memorandum with the court:

(i) stating its position on the need for the extrinsic evidence offered by the other party; and
(ii) stating whether, if the court hears the extrinsic evidence offered by its opponent, it wants to present extrinsic evidence as well; and, if so, providing the information required under subsections (i)-(iii) in part b. above.

d. Ten (10) days before the date of the Markman hearing, the court shall issue an order stating:

(i) whether it will receive extrinsic evidence, and if so, the particular evidence it will receive; and
(ii) whether the extrinsic evidence in the form of testimony shall be the affidavits already filed, or in the form of live testimony from the affiants.

Expert Witnesses

1. On April 15, 2002 the parties shall exchange expert reports, which reports shall be in accordance with F.R.C.P. 26(a)(2)(B) ("Initial Expert Reports"). The Initial Expert Reports from each party shall deal with the issues on which that party has the burden of persuasion.

2. On May 15, 2002 the parties shall exchange Rebuttal Expert Reports shall be exchanged. Rebuttal Expert Reports shall also be in accordance with F.R.C.P. 26(a)(2)(B).

3. Every expert report shall begin with a succinct statement of the opinions the expert expects to give at trial.

4. Unless leave of court is applied for and given, there shall be no expert testimony at trial on behalf of the party having the burden of persuasion on any issue not covered in that party's Initial Expert Report.

5. Unless leave of court is applied for and given, an expert shall not use or refer to at trial any evidence, basis or grounds in support of his/her opinion not disclosed in his/her expert report.

6. Unless leave of court is applied for and given, no expert reports other than the Initial and Rebuttal Reports described in paragraphs 1 and 2 above shall be permitted.

Patent Owner/Prosecution Counsel Communications

3. Communications during patent prosecution between the inventor and owner of the patent(s)-in-suit on the one hand, and counsel prosecuting the patent(s) on the other, are presumptively privileged, and need not be produced by plaintiff unless defendant can state:

   a. with reasonable specificity what information it believes it will find in such communications, and the basis for such belief; and
   b. for what purpose it would use the information at trial.

   If defendant makes the required showing, the documents in question will be produced to the court for *in camera* inspection to determine whether they do, in fact, contain the information specified by defendant and whether it could be used for the purpose proposed by defendant. The documents will be produced to defendant only if both conditions are satisfied.

Trial

This case shall be ready for a **Jury** trial on November 1, 2002 or upon resolution of any pending dispositive motions. Anticipated length of trial is ten (10) to twenty (20) days.

Dated: September 14, 2001

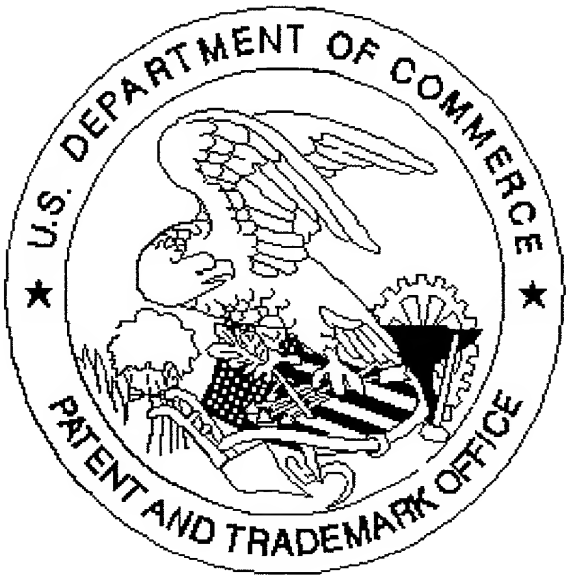
Susan Richard Nelson

Susan R. Nelson
United States Magistrate Judge

No further extensions will be granted

United States Patent & Trademark Office

Office of Initial Patent Examination -- Scanning Division



☐ Page(s)_____of_____ were not present for scanning.
(Document title)

☐ Page(s)_____of_____were not present for scanning.
(Document title)

☐ ***Scanned copy is best available.*** some drawings are dark.